

CORRELATION BETWEEN TERTIARY EDUCATION AND PHARMACEUTICAL INDUSTRY REQUIREMENTS FOR REGULATORY AFFAIRS PHARMACISTS

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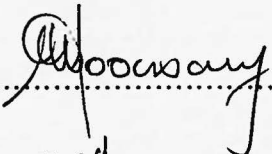


A Research Report submitted to the Faculty of Health Sciences, University of Witwatersrand,
Johannesburg, in fulfilment of the requirements for the degree of Master of Science in Medicine
Pharmacotherapy

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DECLARATION

I, Marlene Rose Moonsamy, hereby declare that this research report is my own work. It is being submitted for the degree of Master of Science in Medicine (Pharmacotherapy) at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Signature.....

Signed on the ...^{2nd}...day of...JUNE.....2016

ABSTRACT

In the pharmaceutical sector, the health of the public is protected by medicines regulatory authorities who enforce regulatory practices to be executed by pharmaceutical companies. In South Africa, the Medicines Control Council (MCC) describes these practice requirements via guidelines, which are based on the Medicines and Related Substances Control Act 101 of 1965. The Regulatory Affairs Department is often the first point of contact between the regulatory authority and the company. Regulatory affairs pharmacists therefore require broader skill sets than scientific and technical skills. Global expansion of regulatory affairs has resulted in significant skills shortage, for which a lack of education in regulatory affairs is partially responsible. Lack of communication between academia and industry further contributes to this skills shortage. In South Africa, the Pharmacy School curricula are approved by the South African Pharmacy Council (SAPC) in keeping with The Pharmacy Act 53 of 1974. Regulatory practices however, are determined by the Medicines and Related Substances Control Act. The aim of this study was to assess if there are inconsistencies in regulatory affairs between the pharmacy curriculum and job descriptions of regulatory affairs pharmacists, and to determine if graduating pharmacists entering industrial pharmacy are equipped for their role in regulatory affairs. The objectives were to examine regulatory education and regulatory practices in industry to assess deficiencies in the required competencies of a regulatory affairs pharmacist. The appropriate sections in Pharmacy curricula from all eight Pharmacy Schools in South Africa were examined to assess the level to which regulatory affairs is taught, and the job descriptions of regulatory affairs pharmacists were examined to assess the functional competencies required. Survey studies were conducted in the Pharmacy Schools and Pharmaceutical Industry to understand the gaps between what is taught and what is required in industry practice. The results showed that B.Pharm undergraduates were insufficiently prepared for their role in regulatory affairs, once they entered the Pharmaceutical Industry sector. Regulatory Affairs education is covered partially at undergraduate level but in some detail at a post-graduate level, in some Pharmacy Schools. Improvements are required to the current B.Pharm curricula, taking into account the Medicines Act 101 of 1965 and with MCC Guidelines, to accommodate regulatory affairs education. Collaboration between academia and industry has been proposed and employed in other countries and have been shown to be successful, hence this is also recommended for South Africa with most participants expressing a willingness to do so..

DEDICATION

*I dedicate this research report to my
mother Sharon and my late father
Moonsamy (Dan,)*

*For your love, prayers and support,
and for believing in my desire and
potential to pursue studies in the medical field.*

*This is also in memory of my late sister Esther,
who passed away in December 1997 after a
long battle with leukaemia.
Your struggle has been my motivation to study
further. I will always love and miss you.*

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LIST OF ABBREVIATIONS

Abbreviation	Meaning
B.Pharm	Bachelor of Pharmacy Degree
CAPA	Corrective And Preventative Action
CCDS	Company Core Data Sheet
CMC	Chemistry, Manufacturing and Controls
CTD	Common Technical Document (dossier)
DoH	Department of Health
eCTD	Electronic Common Technical Document (dossier)
FPRR	Final Product Release Responsibility
GMP	Good Manufacturing Practices
HSA	Health Science Academy
MBR1	Medisynebeheerraad 1
MRF	Medicines Registration Form
MCC	Medicines Control Council
PICS	Pharmaceutical Inspection Cooperation Scheme
PSUR	Periodic Safety Update Reports
QA	Quality Assurance
SAPRAA	South African Pharmaceutical Regulatory Affairs Association
SAHPRA	South African Health Products Regulatory Agency
SAPC	South African Pharmacy Council
SEP	Single Exit Price
SOP	Standard Operating Procedure
WHO	World Health Organisation
ZACTD	South African Common Technical Document (dossier)

1 CHAPTER 1: GENERAL INTRODUCTION

It is the responsibility of national governments all over the world to protect the health of the public. In industrial pharmacy this is done by establishing robust medicines regulatory authorities (MRA), which are accountable to the government and the public and which practise transparent decision-making processes (Medicines Regulatory Support, 2016).

1.1 Regulatory practices

Regulatory practices are established by regulatory authorities, and encompass a set of activities to be executed by pharmaceutical companies, to ensure the protection of the public by controlling the safety, quality and efficacy of medicines, during their development, manufacture, packaging, quality controls, and marketing (Dheyongera, 2011); (MCC Guideline 2.01, 2012). Some regulatory practices to be maintained are the following: Ensure appropriate manufacture, storage, distribution and dispensing of medicines; health professionals and patients must be provided with the required information to help them to use medicines rationally; promotion and advertising of medicines by the industry must be fair, balanced and aimed at rational drug use; access to medicines must not be hampered by unjust regulatory practices and illegal manufacture and trade of medicines must be detected and appropriately sanctioned to prevent the public from obtaining access to them (Medicines Regulatory Support, 2016).

1.2 Current situation

Globally, the regulation of medical products has been expanding since the early 20th century and has now ‘mushroomed’, resulting in significant strains on experienced regulatory affairs professionals. The shortage of regulatory affairs professionals is seen as ‘massive’ with the expectation that regulatory demands will continue to increase (Robinson, 2006). In each country, the capacity to provide adequate pharmaceutical services depends on two workforce needs i.e. an appropriately trained pharmacy workforce and a committed academic workforce to train new pharmacists (Anderson, et al., 2009).

1.3 Aim

The aim of this study was to assess the correlation between education and regulatory practices in industry by examining the undergraduate curriculum of the Bachelor of Pharmacy degree offered by Pharmacy Schools in South Africa, and job functions carried out by pharmaceutical companies. At the end of the study, proposals to improve the training and performance of regulatory affairs pharmacists were presented.

1.4 Objectives of Study

The objectives were to compare regulatory education and industrial practices as follows to assess deficiencies in the required competencies of a regulatory affairs pharmacist:

- i. The appropriate section in Pharmacy curriculum from all eight Pharmacy Schools in South Africa to assess the level to which regulatory affairs is taught
- ii. Job descriptions of regulatory affairs pharmacists to assess the functional competencies required.

2 CHAPTER 2: LITERATURE REVIEW

2.1 Why Regulatory Affairs

In the late 1950's and early 1960's a drug called thalidomide, which is a hypnotic and sedative, and which was believed to help with morning sickness, was prescribed to pregnant women in 46 countries around the world. As a result about 10 000 babies were born with phocomelia (a deformity where limbs are shorter than normal) (Medical Dictionary, 2016). This catastrophe gave rise to the improvement of medicine regulatory systems in some countries including the United Kingdom (UK), United States of America (USA) and Europe. In the USA the Drug Amendments Act of 1962 was passed, which required that all new drug applications be approved by the FDA (Food and Drug Administration). This was to ensure that new drugs were both effective and safe. At the same time it became compulsory for medicine manufacturers to comply with Good Manufacturing Practices in their facilities, which the FDA was also authorized to approve (Rago & Santoso, 2008). In South Africa, the Medicines and Related Substances Control Act (Act 101 of 1965) was passed. This has ensured that over the past 50 years, the Medicines Control Council (MCC) has become a medicines regulatory authority with internationally recognised standards (History, 2013).

Due to the fact that medicines are not normal consumer products, professional advice is required to guide consumers and patients on how and when they should be taken, and how to weigh their benefits and risks. Healthcare professionals today do not have the capacity to make fully informed decisions about all aspects of medicines without special training and easy access to the right information (Rago & Santoso, 2008). Furthermore, regulatory affairs is a broad area which is updated often, and professionals are challenged to keep abreast (Sreedhar, et al., 2005). It is therefore the responsibility of pharmaceutical companies, specifically regulatory functions to ensure that sound medical, scientific and technical knowledge and skills are applied while operating within a legal framework.

2.2 General Scope of Regulatory Practice in Industry

The quick and efficient access of medication to patients may be partially attributed to the speed at which marketing approval for specified products is obtained from regulatory agencies. At the same time, the Pharmaceutical Industry is the most regulated of all industries, therefore one of the ways to ensure quicker access to safe, efficacious medicines is to ensure that the regulatory affairs department is well equipped (Kirby-Smith, 2012), (Sreedhar, et al., 2005), (Khar, et al., 2011).

Regulatory affairs pharmacists provide more than scientific and technical support to their internal and external stakeholders. Their scope of practice includes being familiar with legislation governing medicine registrations; compiling medicine registration applications for human, veterinary, biological or homeopathic medicine; managing the registration process; controlling pharmaceutical advertising; updating and maintaining regulatory licences and supporting the sales and marketing functions in a company (Health Science Academy, 2013).

An understanding of the complete drug development process is also important when determining the regulatory strategy for successful registration approval of a product. In addition, expert scientific knowledge relating to product development and the clinical basis of use must be well understood. Regulatory affairs pharmacists are expected to be experts in the technology of the products they manage, since this reinforces their regulatory practices (Kirby-Smith, 2012), (Robinson, 2006). It therefore stands to reason that their skill sets must be broader than having only scientific and technical qualifications.

Most companies operate on a multinational basis making exportation of medicines a key component of their business. This requires that regulatory affairs pharmacists continually monitor, analyse and interpret the practices and requirements of regulatory authorities in their export markets in order to inform their internal stakeholders of regulatory trends and matters in the respective export markets (Dheyongera, 2011).

2.3 Regulatory Affairs Education – The Global Situation

Various studies around the world have shown that the lack of education in regulatory affairs is partially responsible for the shortage of regulatory affairs professionals. In the UK, pharmacy students did not seem to have sufficient information about the Pharmaceutical Industry, as most Pharmacy Schools gave little attention to industrial pharmacy compared with other careers. Pharmacists in industry however, perceive regulatory affairs to be a prominent career opportunity. It is clear that undergraduates need to be made aware of the opportunities to develop their careers in regulatory affairs (Kirby-Smith, 2012).

In the US and Europe, continuing education by regulatory affairs organizations, has been useful in developing and maintaining the regulatory knowledge of their members (who are already involved in regulatory affairs), but a possible further solution may be to educate new regulatory affairs professionals in academic institutions. While practical experience is preferred over

academic qualifications, employers and academic institutions are both perceived to bear the responsibility of filling the gaps by partnering with each other to meet the needs of students and prospective employees (Robinson, 2006).

In Australia, the Pharmaceutical Education Council (PEC) which was set up to assess the skills gap between government and tertiary institutions, maintains that “a lack of communication between industry and academia means that industry do not know what is available to them and academia do not know what industry wants” (Report on Skills Gap, 2007, page 91). They therefore encouraged a two-way partnership between industry and academia. Of the technical skills found to be lacking in new graduates, training and experience in regulatory affairs featured at the top of the list (Report on Skills Gap, 2007).

In India, the Pharmaceutical Industry is a rapidly growing sector, making it part of the global competition. The Pharmaceutical Industry is one of the most highly regulated industries; coupled with the current global competition, the progressive need for regulatory affairs professionals cannot be over emphasized. It is of urgency that the current requirements of Pharmaceutical Industries be incorporated into the standard curriculum of Pharmacy Schools. To address this issue, two universities in India have taken the initiative to offer Pharmaceutical Regulatory Affairs as a subject in a post-graduate course (Songara, et al., 2011).

In South Africa, no published articles were found to describe possible inconsistencies in the current regulatory framework (legislation, practises and trends) between pharmacy education and industry practices, such as a comparison of legislative requirements. An article was however published to explain what regulatory affairs encompasses and to highlight the need for collaboration among various stakeholders to improve regulatory affairs knowledge and skills (Dheyongera, 2011). The content from this article is cited in relevant parts of Chapter 2.

2.4 South Africa – The Pharmacy Act (Undergraduate Curricula)

With regard to pharmacy education, courses offered by Pharmacy Schools are registered and approved by the South African Pharmacy Council (SAPC) for professional reasons. The SAPC is responsible for establishing and overseeing standards for education and licence registrations (Summers, et al., 2001). According to The Pharmacy Act 53 of 1974 (Pharmacy Act, 2002), the curriculum for the B.Pharm degree requires a minimum of four years of full-time study at a recognised university. Major subjects should include Pharmacology, Pharmaceutical Chemistry, Pharmaceutics and Pharmacy Practice. Each subject is required to be covered over 4 semesters. Supplementary subjects which may be included are General and Organic Chemistry, Anatomy,

Biochemistry, Biology, Biostatistics, Physics, Physiology, Immunology, Microbiology, Pathology and Mathematics. Miscellaneous subjects may include Communication skills, Social and Behavioural Sciences and Computer Literacy (Pharmacy Act, 2002).

Pharmacy education conforms to The Pharmacy Act 53 of 1974, which was amended in 1997, for provisions relating to pharmacy education and training requirements (Pearmain, 2012). The amendment included the addition of seven unit standards, which were prescribed for the education and training of pharmacists to form their scope of practice (Amended Pharmacy Act, 2000). These include the following, which have been quoted directly from Annexure A of The Pharmacy Act: “Unit EL 1 – Organise the manufacturing, compounding and packaging of pharmaceutical products; (ii) Unit EL 2 – Organise the procurement, storage and distribution of pharmaceutical products; (iii) Unit EL 3 – Dispense and ensure the optimum use of medicine prescribed to the patient; (iv) Unit EL 4 – Provide pharmacist initiated care to the patient and ensure the optimum use of medicine; (v) Unit EL 5 – Provide education and information on health care and medicine; (vi) Unit EL 6 – Promote community health and provide related information and advice; (vii) Unit EL 7 – Participate in research to ensure the optimal use of medicine.” (Amended Pharmacy Act, 2000). It is clear from these prescribed unit standards, which lack the mention of regulatory affairs related subjects, that education in regulatory affairs is deemed to not be compulsory for inclusion into the B.Pharm curriculum.

Regulatory practices in industry are determined by the guidelines published by the MCC in keeping with the Medicines and Related Substances Control Act (Act 101 of 1965), and not The Pharmacy Act. In order to provide the best healthcare for patients, it is important that curricula are aligned with actual practice activities (Anderson, et al., 2009). It was noted in a local publication that for some inconsistencies in health legislation, amendments may be required to The Pharmacy Act to bring it in line with The Medicines and Related Substances Control Act. The Pharmacy Act was last amended in 2002 and did not include any amendments related to the educational needs of the Pharmaceutical Industry (Pharmacy Act, 2002). The Medicines Act was also amended in 2002 to include regulations relating to the marketing of medicines (Pearmain, 2012); (Medicines Act, 2002). There is therefore a need to update The Pharmacy Act to provide for these amendments and any other disparities in legislation.

2.5 South Africa - The Medicines Act (Regulatory Practices)

The Medicines and Related Substances Control Act 101 of 1965 (Medicines Act, 2002) covers the following requirements with regards to registration of medicines, in Section 15 of The Act:

- Each application for medicine registration is to be completed on the prescribed form and accompanied by the relevant samples and prescribed fee.
- The duties of the registrar in registering the medicine viz. submitting the application to the MCC for review; ensuring that the application for medicine to be registered is either listed on the Essential Drugs List (EDL)*, or is deemed to be an essential medicine; approve registration if all requirements by MCC have been met; notify the applicant if the requirements have not been met; reject the application if no response is received after notification, or if the response is deemed to be unsatisfactory to the MCC. An appeal may be lodged for rejected applications, within a prescribed period.
- On approval of registration of the medicine, the particulars of the medicine are to be entered into the medicines register and the applicant is to be issued with a medicine registration certificate by the MCC. This medicine will also be issued a registration number by MCC.
- Registration of the medicine is valid for a period of 5 years, subject to conditions that the MCC may determine.
- Applications may be lodged to make amendments to medicines entered into the register, which will require approval by the MCC. These applications will be submitted to MCC by the registrar.
- For amendments that require changes to the registration certificate, the existing certificate will be cancelled and a new certificate issued, once the amendment has been approved.
- Applications may also be made to transfer registration of a medicine to a new holder. Once approved by MCC, the existing certificate will be cancelled and a new one issued to the new holder.

*EDL refers to the list of essential drugs, published by the Department of Health, which is included in the latest edition of the Guidelines for Standard Treatment (Medicines Act, 2002).

The Medicines Act also covers requirements relating to labelling and marketing of medicines in Section 18. Section 18C covers the prescribing of a Code of Ethics for marketing policies of pharmaceutical companies. This is fulfilled by the publishing of the SA Code of Marketing Practice (SA Mkt Code, 2014), which was issued by pharmaceutical trade associations in keeping with the requirements of The Act, to establish responsible, ethical and professional marketing of health products to healthcare professionals and the public. This Code takes into

account advertising and labelling restrictions based on the scheduling status of medicines and the audience to which these medicines are advertised, for example Schedule 0 and 1 medicines may be advertised directly to consumers, but Schedule 2 - 6 medicines may not be advertised directly to the general public, only to health care professionals, and with more restrictions to the content of the advertisement (SA Mkt Code, 2014). A thorough understanding of the marketing code is required, since regulatory affairs is involved in developing marketing concepts and in approving advertising and packaging material (Dheyongera, 2011).

Section 22A of The Act covers the Control of Medicines and Scheduled substances and Section 22C covers the licencing requirements for the premises where manufacturing of medicines occurs (Medicines Act, 2002), which comprises a large part of the regulatory function in industry practices.

By comparing the Pharmacy Act requirements to that of the Medicines Act it is quite clear that there are differences in legislation which directly impact the educational needs for regulatory practices within the Pharmaceutical Industry.

2.6 Regulatory Bodies

2.6.1 World Health Organisation (WHO)

The World Health Organisation (WHO) began in 1948 with headquarters situated in Geneva, Switzerland. They support countries to coordinate government efforts with their stakeholders to achieve health objectives and implement health policies (About WHO, 2016). The activities of WHO relating to regulatory support, includes assessing the regulatory systems for national medicines, providing regulatory information and manuals, providing training opportunities, providing a model website for medicines regulatory authorities (MRA), providing a certification scheme on the quality of pharmaceutical products in international commerce, holding international conferences of Drug Regulatory Authorities and providing international cooperation and harmonisation (Medicines Regulatory Support, 2016).

The WHO has stipulated the activities required by regulatory authorities for effective drug regulation. These include ensuring that the manufacture, import, export and distribution premises for medicines are licenced. All activities are required to comply with Good Manufacturing Practice (GMP) requirements. Medicines must be assessed for safety, efficacy and quality before marketing, and must continue to be monitored for safety, efficacy and quality while marketed. Advertising and promotion of medicines must be monitored, and information provided on the rational use of medicines. Regulatory authorities are required to participate in

regional and international regulatory networks and meetings to address common issues, and promote collaboration (Rago & Santoso, 2008).

2.6.2 Medicines Control Council (MCC)

In South Africa, the statutory body that currently governs the regulation of medicines is the MCC which falls within the Department of Health (DOH), and which was established in terms of the Medicines and Related Substances Control Act 101 of 1965. The main purpose of the MCC is aligned with that of the World Health Organisation (WHO), which is to protect the public by ensuring that medicines sold in South Africa are safe, efficacious and of acceptable quality (Medicines Regulatory Support, 2016); (History, 2013). This purpose is achieved by prescribing standards to govern the manufacture, distribution, sale and marketing of medicines through published guidelines. The MCC also determines the scheduling status of medicines and medicinal substances to control their prescribing and dispensing (MCC Guideline 2.01, 2012).

Part of the mandate of the MCC is to maintain the medicine register, register new medicines, amend entries made in the register, transfer registration certificates, cancel registration of discontinued medicines, approve labelling and advertising of medicines and authorize the sale of unregistered medicines under certain conditions (Medicines Act, 2002). This is to ensure that the safety, quality and efficacy of registered medicines are maintained throughout their life-cycle. Changes which occur to these medicines after registration, must also comply with quality, safety and efficacy requirements as stipulated by the MCC (MCC Guideline 2.08, 2012).

Some technical changes that may take place after medicine registration may be related to manufacturing, packaging and testing sites, manufacturing and testing methods, active and inactive pharmaceutical ingredients and their source of manufacture, and transfer of the marketing authorisation holder (MAH) for products acquired through acquisitions and mergers with other pharmaceutical companies. These changes could impact the formulation, manufacturing procedures, container / packaging material, final packaged product or the shelf life of the product. In the course of these life-cycle changes, it is important to ensure that the product remains within safety, efficacy and quality requirements (MCC Guideline 2.08, 2012).

Clinical changes would affect package inserts and patient information leaflets. Package inserts are leaflets accompanying pharmaceutical products, which contain clinical information about the product. Clinical information includes indications, contraindications, dosing instructions, side effects and warnings. Patient information leaflets are an adaptation of the package insert into consumer language to enable patient understanding of the clinical content. Changes to these

documents would normally relate to safety or efficacy of the medicine, which is monitored by the Pharmacovigilance department within the company. Regulatory affairs personnel provide support to Pharmacovigilance for specific products to ensure that package inserts and patient information leaflets for these products are updated according to regulatory authority requirements and internal company procedures (MCC Guideline 2.01, 2012); (MCC Guideline 2.16, 2013); (MCC Guideline 2.14, 2013); (MCC Guideline 2.33, 2012).

The MCC stipulates the format and data requirements in compiling applications for registration of medicines and applications to make changes to registered medicines, via published guidelines. These guidelines are based on the Medicines and Related Substances Control Act 101 of 1965 and its regulations (MCC Guideline 2.01, 2012). The format of the medicine dossier has changed over the years from MBR1 to MRF1 and more recently to the Common Technical Document (CTD) format. MCC announced in June 2010 that the South African Common Technical Document (ZA CTD) format will be implemented to replace the MRF1 and older MBR1 formats. The deadline for companies to ensure compliance to this requirement for existing registration dossiers is June 2016. The further format conversion from CTD to the paperless eCTD (electronic CTD) is currently in the pilot phase (MCC Guideline 2.26, 2016). These changes in formats are in line with the globally recognised International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines (MCC Guideline 2.24, 2012).

The MCC aligns itself with established regulatory authorities around the world, such as Food & Drug Administration (USA), European Medicines Agency (EMA) and National Regulatory Authorities (European Union), and Ministry of Health, Labour & Welfare (MWH), Japan. It also aligns to Swissmedic (Switzerland), Health Canada (Canada) and Therapeutic Goods Association (Australia), to ensure that regulatory practices in South Africa are harmonized with internationally accepted standards (MCC Guideline 2.01, 2012).

2.6.3 SAHPRA

The MCC is currently undergoing changes to be replaced by a new public entity known as the South African Health Products Regulatory Agency (SAHPRA). It will be a national public entity instead of being situated within the National Department of Health NDOH (as is the current MCC). This means that governance of SAHPRA, its councils, committees and staff will be appointed by a board, but the NDOH will still monitor and review the functioning of this body. SAHPRA will manage registration, regulation and control of health products such as medicines

and medical devices. Due to legislative changes that needed to be passed by Parliament, this transition was in 2011, expected to occur in 2013 (Schaay, et al., 2011). The Medicines and Related Substances Amendment Bill (B6-2014) was eventually passed by parliament on the 10 November 2015 and signed by the President on 24 December 2015 to be published in the Government Gazette No. 39585 (Medicines Amendment Bill, 2015). This long awaited new regulatory body is expected to improve the speed at which medicine registrations are processed (Govt. to establish Institute, 2014).

The regulatory affairs profession is not limited to the Pharmaceutical Industry, but is also extended to country regulatory agencies (Robinson, 2006). Dr Aaron Motsoaledi, who is the current Health Minister in South Africa, recently announced that his department would soon establish the Institute for Regulatory Science, which is being set up with different universities in South Africa, the Gates Foundation, the European Union and WHO. He acknowledged that the number of medicines requiring registration by a regulatory authority is “staggering” but that South African universities do not offer courses in regulatory medicine to train regulators. This institute is therefore intended to be the formal structure to train regulators, and act as a training facility for regulatory pharmacists in industry (Govt. to establish Institute, 2014).

2.7 Challenges for the Regulatory Profession

There is little opportunity to recruit junior regulatory personnel with no working experience, as recruiters seek candidates with even little experience instead of only an academic degree. It is also not certain to what extent regulatory affairs can be taught in an academic environment, instead of allowing this knowledge to be developed by practical work experience. This makes it difficult when recruiting, as recruits could be new graduates from scientific backgrounds with little to no experience in regulatory related skills such as product development and project management, but with a potential and commitment to learning. Other recruits could join regulatory affairs at a senior management level, after having developed their careers in fields such as research and development or clinical practice. They would be more successful candidates as the regulatory recruitment process favours a wide range of previously achieved skills, expertise and experience (Robinson, 2006); (Kirby-Smith, 2012).

The speed of modern communication globally, requires that regulatory personnel are able to address queries raised by regulatory agencies at short notice. This requires that regulatory personnel maintain their knowledge to keep pace with this, new regulatory requirements and other technological advancements related to their products, on a global level (Robinson, 2006).

2.8 Outcomes of Academia – Industry Collaboration

Several countries have explored the option of academia and industry partnerships to narrow the educational and skills gaps. In India, the Banaras Hindu University has been maintaining the B.Pharm curriculum to accommodate the evolution of the pharmacy profession; however it was still noted that the pharmacy courses became outdated due to the rapid advancement in technology and changes in the Pharmaceutical Industry. This necessitated more interaction between academia and industry (Sreedhar, et al., 2005); (Khar, et al., 2011).

Students were within a bureaucratic educational structure and motivated, but without exposure to work related problems and solutions. Employees in industry in comparison were pressured for time to meet deliverables, that they did not have the time to explore their ideas and acquired knowledge further. The key was to connect these students and employees (Khar, et al., 2011).

Training in industry for 15 days or one month was deemed to not be sufficient for a four year course. Students were expected to benefit more from practical approaches in teaching, to allow them more time to understand the subject matter and develop specific skills, therefore the involvement of industry experts were expected to contribute to this approach (Khar, et al., 2011).

The proposal was to have a curriculum where the first two years covered basic pharmacy knowledge and the third and fourth years offered a specialisation subject. The specialisation subject would be split into two parts of one and a half years for methodical understanding and practical training and the second part of six months for project work in industry. For the specialisation subject, a learning centred approach was proposed, where teachers would assume the role of facilitators and students would engage in a structured learning environment to bridge theoretical concepts with practical application. The objective of the revised curriculum was to develop analytical and scientific thinking skills. This course was proposed to run concurrently with the existing course to assess its success before transforming it into a dual B.Pharm – M. Pharm degree (Khar, et al., 2011).

Another study was done in the UK which clearly showed the benefits of collaboration between academia and industry for a course in drug development for medical students. When students evaluated the collaboration module it was found that the most popular sessions were the interactive ones where lectures were changed to problem based learning techniques, and which encouraged student participation. Student knowledge was also shown to have improved at the end of the module. This approach has further steered a more open style of teaching in later

modules. This collaboration also benefitted the participating pharmaceutical company, as tutors formed a better understanding of the requirements for undergraduates, which further improved their courses and skills. The company was also able to develop an induction aid for new employees, from this collaboration module (Stanley, et al., 2005).

An investigative study was done in Australia by the Pharmaceuticals Education Council (Report on Skills Gap, 2007), which highlighted many facets to closing the skills gap between the Pharmaceutical Industry and academia. This study looked at the cultural views of industry vs academia, course structures at universities, and partnering opportunities between industry and academia (Report on Skills Gap, 2007).

There is a perceived tension between industry and academia as their focus is different, and therefore they drive different behaviours. There were suggestions that working in the Pharmaceutical Industry is not viewed as a profession by academia, and industry is less keen to give back to academia. The communication gap between industry and academia may also be as a result of people employed in industry, who rarely go back to academia; therefore academia is not aware of what is expected of graduates. Suggestions were that industry changes its 'mind-set' and invests in long term learning opportunities with academia. Graduates in new positions seem to expect quick career progression without considering the need to be upskilled, which creates a disparity between expectation and reality, when they are employed. To help industry and academia understand each other's' areas would require spending exchanged time in these areas. The risk however is that the usual focus in their respective areas will be compromised. Issues with intellectual property ownership in both academia and industry may make it challenging to have a free working relationship, and this may create the perception that collaboration is difficult (Report on Skills Gap, 2007).

There were suggestions in this study (Report on Skills Gap, 2007) to change the structure of some courses to allow the last year of a four year undergraduate degree to be industry focused, create continuing education modules (designed by industry) and make them available online, and focus on skills such as those needed for regulatory affairs.

Some collaborative opportunities cited in this study (Report on Skills Gap, 2007) were as follows:

- a) Pharmaceutical companies could be made to be part of the university campus

- b) Arrange field trips to pharmaceutical companies to observe what is done in practice
- c) Industry could create holiday working opportunities for students
- d) Industry and academia could have joint / guest lectures
- e) Academia could invite experts in industry to teach modules
- f) Students should be encouraged to work in industry during a 'gap' year
- g) Students could be employed for graduate internships or management rotation programs, which could make them employable after graduation.

3 CHAPTER 3: METHODOLOGY

In order to compare regulatory education and industrial requirements of a regulatory affairs pharmacist, an investigative survey study was conducted.

3.1 Materials

- The main form of collecting data for the surveys was via email and Google Forms.
- Invitations to participate in surveys were sent from the Wits email facility using the researcher's student email address as the sending address.
- The survey tool used was Google Forms.

3.2 Methods

3.2.1 Survey to Pharmacy Schools

In order to review the extent to which regulatory affairs is taught, Heads of Department of Pharmacy at the Universities of Witwatersrand, Western Cape, Limpopo, Kwazulu-Natal, North West, Rhodes and Nelson Mandela Metropolitan Universities (List of Approved Providers, 2016) were contacted and permission acquired to obtain copies of the undergraduate curriculum for Pharmacy Practice from 1st year to 4th year.

Questionnaires were sent via email to academic staff responsible for teaching pharmacy practice, in order to assess their awareness of the functions of regulatory affairs pharmacists, and the level to which regulatory affairs is taught. E-mail addresses of Pharmacy Schools were obtained from the South African Pharmacy Council website (List of Approved Providers, 2016).

The survey forms (see Appendix 1, pages 1-6) for Pharmacy Schools were drawn up on Google Forms. An invitation to participate and an introduction to the survey were provided in the first page. Basic information such as date of completion of survey, designation of person completing survey and name of Pharmacy School were requested. This was followed by a questionnaire to assess the basic understanding of the respondent to requirements for regulatory affairs in industry and to request for details of the content and duration of the B. Pharm undergraduate curriculum and any post-graduate courses relating specifically to regulatory affairs. Suggestions from Pharmacy Schools for any possible inclusions into the B.Pharm curriculum were then requested. To ensure maximum receipt of responses, electronic reminders were sent at various intervals for up to nine months, after which most schools had responded. Information from the remaining schools was obtained via email or from the school's website. The content of the undergraduate and post-graduate curricula from the eight Pharmacy Schools were tabulated to demonstrate common and different themes in a comparative review.

3.2.2 Survey to Pharmaceutical Industry

Pharmaceutical companies and relevant contact details were identified on the list of pharmaceutical companies which are registered with the South African Pharmacy Council (SAPC). This was purchased from the SAPC at minimal cost. This list was checked against the manufacturing pharmacy licence records of the MCC, since the email addresses on the SAPC database were found to be outdated. The SAPC records had in some cases two email addresses per company viz. one for the responsible pharmacist and a general one for the company. As it was difficult to determine which was the correct and current email addresses, survey invitations were sent to both email addresses. All available email addresses were recorded in the researchers email address book.

There are currently 267 manufacturing pharmacies, which are registered with the SAPC (Statistics, 2012). The following formula was used to calculate the number of pharmacies required to participate in this study (sample size) to obtain a 5 % statistical significance (or 95 % confidence level) (Survey Aids, 2012). It was determined in consultation with a statistician from Wits University, that should all 267 pharmaceutical companies currently registered with SAPC be eligible to participate, 185 responses per question would be required to obtain statistical significance.

$$n^* = \frac{z^2 p(1-p)}{d^2}$$

Where Z = 1.96 (e.g. 1.96 for 95 % confidence level)

p = 0.5 (proportion of pharmaceutical companies that have the outcome of interest), d = 0.04 (4 % precision allowed)

Adjusting for the population size, the minimum sample size would be:

$Ss = \frac{n^*}{1 + \frac{n^*}{N}}$ where n^* is the sample size calculated and N is the number of eligible pharmaceutical companies.

The initial number of manufacturing pharmacies provided on the SAPC website was 267 (Statistics, 2012). Subsequently when the contact details were verified, only 254 companies were found to have valid email addresses, therefore this was the maximum number eligible to participate in this survey. The initial sample size required to provide a confidence interval (CI)

of 95 % with a significance level (p-value) of 0.5 was 185. Of the 254 pharmaceutical companies invited to participate, only 50 responded. This includes the companies which were originally meant to be excluded based on the inclusion and exclusion criteria. Inclusion criteria were pharmaceutical companies which are registered with SAPC, which have a central in-house regulatory department, and which manufacture or import ethical, generic or consumer (OTC) medicines. Exclusion criteria were pharmaceutical companies which manufacture or import biological medicines, medical devices, veterinary medicines and complementary medicines. These companies have now been included and their responses will be included in the results. Since the number of responses was 50, the CI obtained with the current sample of 50 was 47 % with a significance level of 0.5; therefore the results of this study have been limited due to the number of responses received.

The survey forms (Appendix 2) for pharmaceutical companies were drawn up on Google Forms and invitations to participate were sent via email. Letters were addressed to The Responsible Pharmacist / Human Resources Manager, stating the purpose of the study. The first page contained the introduction to the survey. Basic information such as date of completion of survey, designation of person completing survey and details about the company were requested next. These questions included whether the company was registered with the South African Pharmacy Council, whether they had an in-house regulatory affairs department and the type of products manufactured or imported. This was to take into account the inclusion and exclusion criteria, which were later removed for the reasons explained above.

Job functions were listed and pharmaceutical companies were requested to indicate if these were practised at their organisations, and listed in the job description of a regulatory affairs pharmacist (See Appendix 2, pages 3 -5). This was to assess company requirements to fulfil the functions of a regulatory role.

Details of job descriptions were tabulated to list broad functional areas. The responses for these job descriptions were compared with the undergraduate curricula and regulatory affairs scope of practice, to determine the extent to which regulatory functions are covered in the curriculum.

This was followed by a leadership questionnaire (see Appendix 2, pages 6–8) to assess the view of pharmacy education by industry and understand competency needs. This was further followed by a detailed questionnaire relating to competencies of recent graduates who were employed as regulatory affairs pharmacists (See Appendix 2, pages 8-10). Finally respondents were invited to provide suggestions to be included to the current B. Pharm curriculum (See Appendix 2, page

10). To ensure maximum receipt of responses, electronic reminders were sent at various intervals for up to nine months. When it was noted that no further responses from pharmaceutical companies were being received, the survey was closed due to time limits to complete study.

Proposals for collaboration between academia and industry were offered in surveys to both Pharmacy Schools and pharmaceutical companies to assess the willingness to partner with each other.

Results from the various surveys were also compared to the published legislative requirements. Once results were collated and analysed, each sector was assessed for deficiencies and possible solutions proposed.

3.3 Statistical / Data Analysis

Responses were collated and automatically tabulated by the survey tool used, viz. Google Forms, which is designed to collate and analyse responses.

For qualitative analysis, comparison of responses was collated where appropriate, and for quantitative analysis statistics calculations were used to determine if there was significance in the responses. Qualitative data was used to support quantitative where relevant.

A statistician from Wits University was consulted for advice on the appropriate tests to be used to analyse noticeable trends for key questions and it was decided that frequencies, means and medians would be the primary means of descriptive analysis.

The tabulated results from the survey for Pharmacy Schools and pharmaceutical companies were captured on the statistics software, *Minitab 17* to calculate the relevant stats for each question. The results have been tabulated and depicted graphically for each question where applicable, with accompanying explanations.

For the survey to the Pharmacy Schools, analyses involved summary stats of each item (frequencies or mean/median score), or items were grouped into themes where relevant, and the trends in responses discussed. For the open ended questions, thematic analysis was done to identify popular responses.

The analysis of the questionnaires to the Pharmaceutical Industry on regulatory affairs practices was done by using frequencies or means/ median scores or means/median of total score.

Analysis of leadership questionnaires involved frequencies and percentages, since the responses were categorical.

For the section relating to job functions carried out by pharmaceutical companies, and competence of recent graduates, each possible response was denoted as a numeric variable (-1, 0 or 1) and T-tests were done for each response.

4 CHAPTER 4: RESULTS

4.1 Pharmacy School Survey – Regulatory Affairs Knowledge

Of the 8 Pharmacy Schools invited to participate, only 7 chose to participate. Collective and individual email reminders were sent consistently for at least seven months after the surveys were meant to be closed, and due to time restrictions was eventually closed after 9 months from initial circulation. Curriculum information for the 8th school was obtained from the school's website. Some schools that participated did not completely answer the open questions related to undergraduate and post-graduate curricula for regulatory affairs. In these cases, the relevant information was sourced from the respective websites of the Pharmacy Schools.

Some statements were assessed in the curriculum section of the survey where participants had to choose the best option from this list to describe their view of regulatory affairs. The options were strongly agree, agree, neutral, disagree or strongly disagree.

The statements which were assessed and the corresponding results follow in percentages in Table 4.1. The results in Table 4.1 indicate that Pharmacy School participants are fairly well equipped with a basic knowledge of regulatory affairs, which the survey assessed in questions 1 to 9. Most responses were either strongly agree (2) or agree (1). For question 10 most participants (71.4 %) agreed strongly that they were aware of the need for pharmacy students to be fully equipped in regulatory affairs by the time they graduated, however for question 11, which enquired about a regulatory affairs module being in the undergraduate curriculum, the maximum response was “neutral” at 42.9 %. This indicates that these participants were not aware of a regulatory affairs module and further denotes a discrepancy in what is known to be required to what is actually being taught at Pharmacy Schools. The mean for most responses was 1 or greater than 1, indicating on average an agreement to most statements assessed.

For the purposes of statistical analysis, these statements listed below were allocated a numerical value viz. strongly agree = 2, agree = 1, neutral = 0, disagree = -1 and strongly disagree = -2, which correspond to the X-Axis points in the graphs in Figure 4.1 and Figure 4.2 below. The Y-axis represents the number of responses from pharmacy school participants. The graphs (1-10) depict the specific responses by Pharmacy School participants for the statements numbered 1 to 10, which are predominantly in agreement or strongly in agreement with the statements assessed.

Table 4.1. Responses from Pharmacy School Questionnaire - Regulatory Affairs Knowledge (1-11)

Question No.	Survey Question / Statement	Strongly agree (2) in % (n) N=7	Agree (1) in % (n) N=7	Neutral (0) in % (n) N=7	Disagree (-1) in % (n) N=7	Strongly Disagree (-2) in % (n) N=7	Mean	SD
1.	I am familiar with the concept of “regulatory affairs” in Pharmaceutical Industry	85.7 (6)	14.3 (1)	0	0	0	1.86	0.38
2.	I am familiar with the requirements of regulatory affairs in industry	42.9 (3)	28.6 (2)	14.3 (1)	14.3 (1)	0	1.00	1.16
3.	I am familiar with the various ACTs (legislation) governing regulatory practices in South Africa.	71.4 (5)	14.3 (1)	0	14.3 (1)	0	1.43	1.13
4.	I am familiar with the different and changing FORMATS of the registration dossier viz. MBR1, MRF, CTD, eCTD	57.1 (4)	14.3 (1)	14.3 (1)	14.3 (1)	0	1.14	1.22
5.	I am familiar with the CONTENT of the registration dossier for the various formats – MBR1, MRF, CTD, eCTD.	28.6 (2)	42.9 (3)	14.3 (1)	0	14.3 (1)	0.71	1.38
6.	I understand the role and functions of the MCC (Medicines Control Council)	85.7 (6)	14.3 (1)	0	0	0	1.86	0.38
7.	I am familiar with the guidelines published by the MCC	42.9 (3)	57.1 (4)	0	0	0	1.43	0.53
8.	I am familiar with the various trade associations which exist to support the Pharmaceutical Industry in SA, including SAPRAA (South African Pharmaceutical Regulatory Affairs Association)	28.6 (2)	57.1 (4)	0	14.3 (1)	0	1.00	1.00
9.	I am familiar with the SA Marketing Code of Practice, which describes the regulations for the advertising of medicines in South Africa	14.3 (1)	71.4 (5)	0	14.3 (1)	0	0.86	0.90
10.	I am aware of the need for pharmacy students in South Africa to be well equipped in regulatory affairs functions by the time they graduate	71.4 (5)	14.3 (1)	0	14.3 (1)	0	1.43	1.13
11.	The undergraduate B.Pharm curriculum at this Pharmacy School consists of a regulatory affairs module which covers the main requirements of regulatory functions	28.6 (2)	28.6 (2)	42.9 (3)	0	0	0.86	0.90

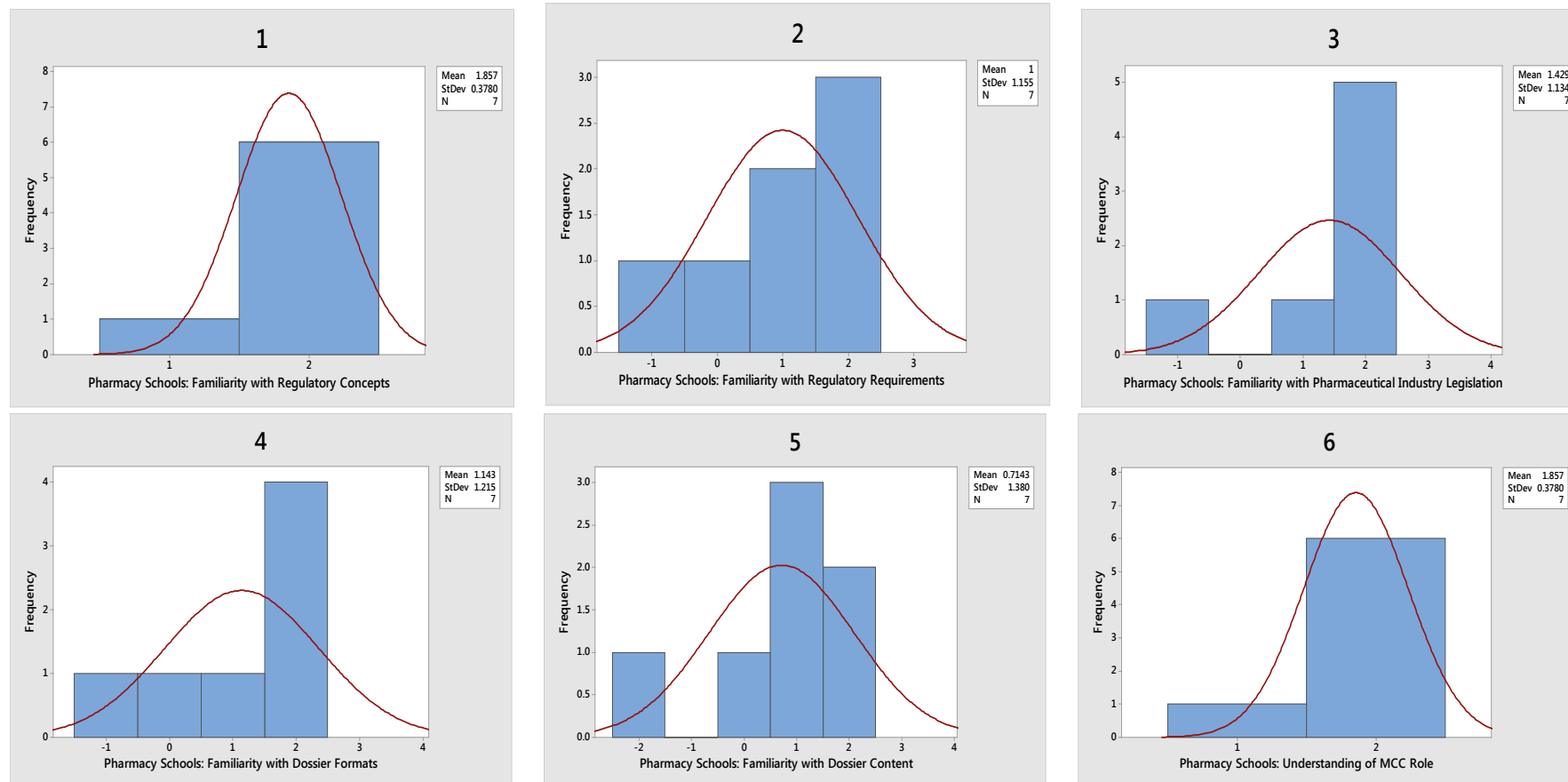


Figure 4.1. Pharmacy Schools Questionnaire: Regulatory Affairs Knowledge (Graphs 1-6)

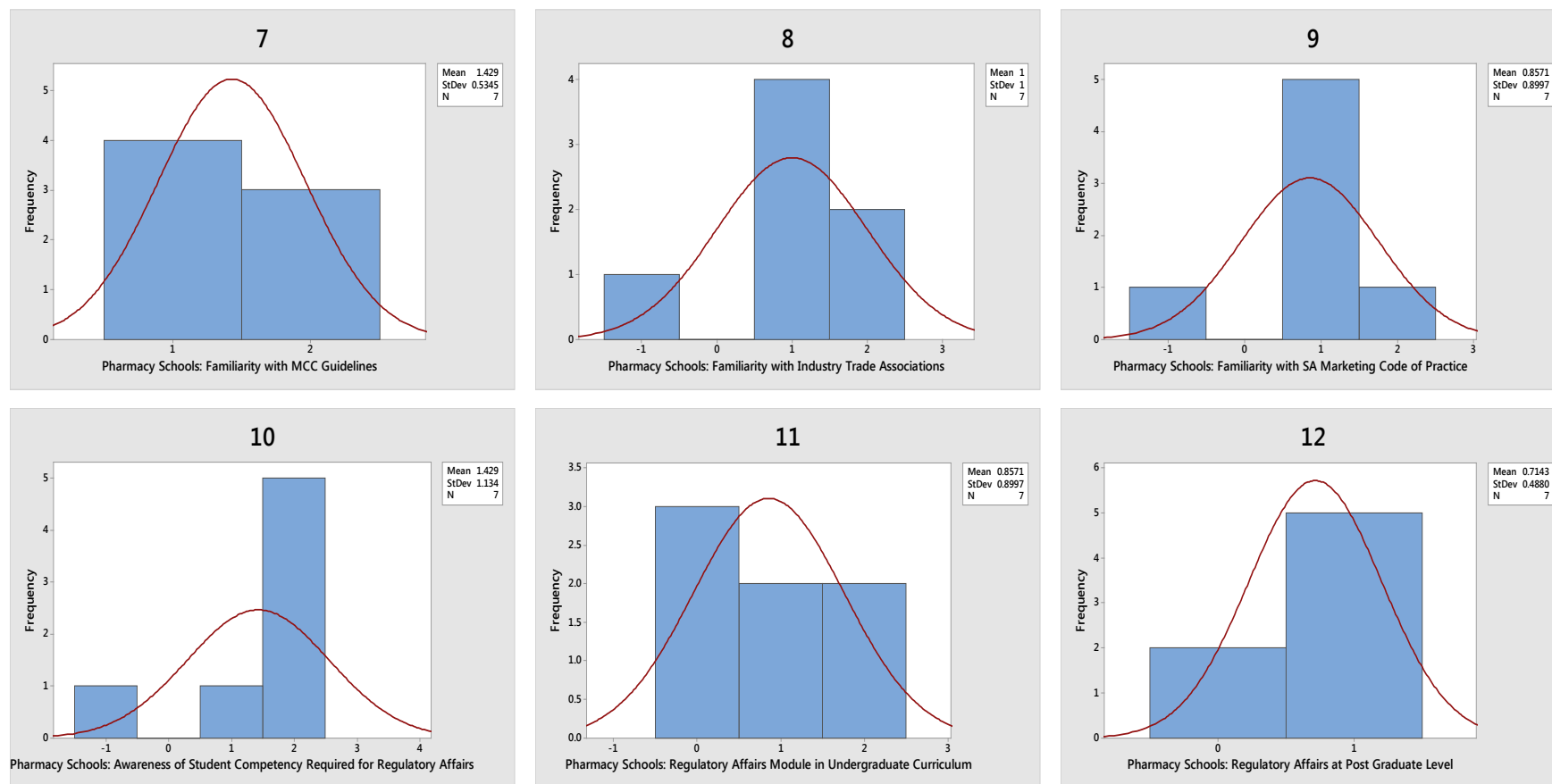


Figure 4.2. Pharmacy Schools Questionnaire: Regulatory Affairs Knowledge (Graphs 7-12).

For statement 11 (Figure 4.2, Graph 11) the highest responses were for the “neutral” option. The mean for most questions assessed were 1 or greater than 1, indicating that on average participants were in agreement with the statements made.

Two further statements were assessed for which the options ‘yes’, ‘no’ or ‘don’t know’ were provided. The statements were as follows and the results follow in Table 4.2:

Table 4.2. Responses from Pharmacy School Questionnaire – Curriculum

Question No.	Survey Question / Statement	Yes % (n) N=7	No % (n) N=7	Don't know % (n) N=7	Mean	SD
12	This Pharmacy School provides regulatory affairs education at a post-graduate level.	71.4 (5)	28.6 (2)	0	0.71	0.49
13	This Pharmacy School is willing to collaborate with the Pharmaceutical Industry and trade associations to develop a curriculum for regulatory affairs, should there be a need	100 (7)	0	0	N/A	N/A

Pharmacy School participants indicated that 28.6 % strongly agree and 28.6 % agree to having a regulatory affairs module at undergraduate level at their school. Most (71.4 %) also said “yes” to having a post-graduate regulatory affairs module. This infers that some Pharmacy Schools may have noted that there is a lack of a regulatory affairs module at undergraduate level, and may have made amends to include this at a post-graduate level. This is further depicted in graph 12 of Figure 4.2 above.

All Pharmacy Schools that participated were unanimous in their response (100 %) regarding willingness to collaborate with Pharmaceutical Industry and trade associations to develop a curriculum for regulatory affairs, should there be a need.

4.2 Course Content and Subjects for B.Pharm Degree and Post-graduate Courses

The next part of the survey related to content of the B. Pharm degree and other courses which provided regulatory affairs education at both undergraduate and at post-graduate level. This section allowed free text responses from Pharmacy Schools to ensure completeness of responses. Of the 8 schools invited to participate, one school did not participate in the survey study and one school was reluctant to provide information for both the undergraduate and post-graduate curricula. For the schools that did not

participate or provide curriculum information, the required information was obtained from the respective schools' website for both undergraduate and post-graduate curricula. Only 4 Pharmacy Schools provided information for post-graduate education, therefore the researcher examined the various schools' websites for content of their post-graduate curricula. This has been collated in Table 4.3 with an overall finding summarised for each school (Pharmacy Degree Structure, 2016); (Health Sciences, 2016); (Prospectus 2016); (Faculty of Health Sciences, 2016); (Modules for Msc(Med), 2016).

Table 4.3. Course Content for Undergraduate and Post-graduate Curricula (1-8)

School No.	Undergraduate Curriculum Info	Post-graduate Curriculum Info	Overall Findings
1.	"There is no specific regulatory course at undergraduate level. Different aspects of it are covered in different modules of Pharmacy Practice, Pharmaceutics, Pharmacology and Pharmaceutical Chemistry."	Information for this school was sent via email. This school has an online collaboration program for a Master in Science Degree for Regulatory Sciences.	Regulatory education is evidently covered less specifically in undergraduate courses and more specifically in post-graduate courses
2.	"Medicines governance, which includes registration of medicines, is covered in a 6 week module that addresses industrial pharmacy. It is integrated into other modules such as Medicines Manufacture (large scale), and Introduction to the Practice of Pharmacy, and in the Introduction to the various dosage forms. Students also spend one month of "work based learning" in the Pharmaceutical Industry."	This school offers a Bachelor's degree in Pharmaceutical Sciences – Registration of Medicines block course part time over one year.	Regulatory education is evidently covered partially in undergraduate course and specifically in post-graduate education
3.	"Integrated knowledge is applied to product development and formulation in the compounding, manufacturing, distribution and dispensing of pharmaceutical products. Medication is compounded, manipulated and prepared in compliance with Good Pharmacy Practice (GPP), Good Manufacturing Practices (GMP) and/or Good Clinical Practice (GCP). The manufacture, packaging and registration of pharmaceutical products are managed in compliance with GMP and GCP (range of pharmaceutical	This school offers PhD Studies /Research, Masters Research (relating to regulatory affairs)"	Regulatory education is evidently covered partially in undergraduate course and specifically in post-graduate course

School No.	Undergraduate Curriculum Info	Post-graduate Curriculum Info	Overall Findings
	products includes but is not limited to medicines, veterinary products, biological products).”		
4.	“Medicines Registration (4 X 35 minute lectures). Pharmaceutical Product Development (4 X 35 minute lectures) and GMP (34 X 35 minute lectures) are covered in the Pharmaceutical Manufacturing Practice module, which is a compulsory module in the final year of the B.Pharm program. Medicines registration is also included in an elective module on the Pharmaceutical Product Development in the final year.”	“An awareness of the MCC and its functions is created in the Higher and Advanced Certificate Programs in Pharmacy Support (Pharmacy Technical Assistant and Pharmacy Technician Programs). Pharmaceutical Product registration is covered in detail in the Masters in Pharmacy (Industrial Pharmacy) program in the Pharmaceutical Product Development module.”	Regulatory education is evidently covered partially at undergraduate level and specifically at post-graduate level.
5.	Information was obtained online as this Pharmacy School did not participate in the survey. It was noted that the curriculum is decided by the SAPC, and that it may have a different emphasis to other Pharmacy Schools in South Africa. The fourth year curriculum includes an Elective / Project which lists Drug Regulation as an option.	This school did not participate in the survey hence the required information was sourced from the school’s website. The information for post-graduate studies were not clear about the course content for the Masters degrees. The doctorate course did not include regulatory affairs, but had a clinical focus.	Regulatory education is evidently covered partially as an elective at undergraduate level and not clearly specified for post-graduate education.
6.	Taught by School 2 as part of the collaboration”, therefore inferring that the course is the same as that taught by School 2.	Taught by School 2 as part of collaboration”, therefore inferring that the course is the same as that taught by School 2.	Same as School 2 (Regulatory education is evidently covered partially in undergraduate course and specifically in post-graduate education)
7.	This information was not provided by the school, and was therefore sourced from the school’s website. The modules from first year to fourth year did not specify any mention of industrial pharmacy or regulatory affairs.	This school provided an email contact to request information, but since the email address was incorrect this option was not pursued. This information was however eventually obtained from the school’s website. This school offers a Master’s degree, which includes a module on Regulatory Affairs and Medicine Registration. This module covers	Regulatory affairs is evidently not specifically taught at undergraduate level but is specifically taught at post-graduate level.

School No.	Undergraduate Curriculum Info	Post-graduate Curriculum Info	Overall Findings
		aspects of the Pharmacy Act, the Medicines and Related Substances Control Act and the essentials of Medicine Registration.	
8.	The participant was reluctant to provide this information; therefore it was sourced from the school's website. The course description mentioned pharmaceutical production, which is one part of industrial pharmacy, but failed to mention industrial pharmacy or regulatory affairs.	The participant was reluctant to provide this information therefore this was sourced from the school's website. This school has a number of "short learning programs" for B.Pharm graduates, some of which are for Legislation and Quality Control and Quality Assurance in the Pharmaceutical Manufacturing Industry, however there was no specific mention of Regulatory Affairs education.	Regulatory affairs is evidently not specifically taught at both undergraduate and post-graduate levels.

From these responses, it is apparent that Pharmacy Schools are aligned with The Pharmacy Act requirements for the undergraduate curriculum to include medicines registration either in the main curriculum or as an elective in the final year of study. When provided as an option for an elective, this would not be selected by all B.Pharm students. It is clear that 6 of the 8 Pharmacy Schools have included the registration of medicines into other courses including in post-graduate courses. While the undergraduate curricula of most schools are aligned with the requirements of The Pharmacy Act (Act 53 of 1974), they do not satisfy the regulatory educational needs which are highlighted in The Medicines Act (Act 101 of 1965). Overall, regulatory education is covered partially at undergraduate level, and more specifically and holistically at post-graduate level, in most schools.

4.3 Suggestions for Future Regulatory Affairs Module

Suggestions were requested from Pharmacy Schools for areas in regulatory affairs to be covered in a future regulatory affairs module. This was provided as follows in Table 4.4:

Pharmacy Schools provided brief feedback (as mentioned below) for this section, but it was noted that all suggestions to develop a curriculum were completely different from each other. These responses were brief and unclear, but one participant expressed a need for "practical hands on workshop with appropriate actual examples". This infers that the participant is aware that understanding the theory of the various aspects of pharmacy is insufficient to equip pharmacists for regulatory affairs practices in industry.

Table 4.4. Suggestions for Future Regulatory Affairs Module

School No.	Suggestion/s
2	“Practical hands-on workshops with appropriate actual examples where possible”
3	“None”
7	“Needs to focus on industry and regulator differences; focus on evolving mechanisms”
8	“Each university should develop their own curriculum”

Another suggested focusing on regulatory and industry differences and evolving mechanisms, indicating that this participant is aware of the constantly changing regulatory environment. The suggestion that “each university should develop their own curriculum” was noted as offering more options to future pharmacists.

4.4 Pharmaceutical Industry Survey – Basic Information

The first part of the survey (Appendix 1, page 2) consisted of basic information about the organization which also contained questions on the exclusion criteria, to allow filtering of results to exclude the “other” product manufacturers viz. veterinary health, complementary medicines, medical devices and vaccines. Due to the minimal number of responses received, it was subsequently decided to include all types of medicine manufacturers. Inclusion criteria included companies which have an in-house regulatory affairs department, and are registered with the South African Pharmacy Council (SAPC).

The questions for the first part of the survey were as follows:

a) Designation of Person completing questionnaire.

This information was requested to assess whether participants were leaders in regulatory affairs. The responses to this question were quite diverse although the main responses were Responsible Pharmacist, Head of Regulatory Affairs or Regulatory Affairs manager. In some cases the role of Responsible Pharmacist was combined with Regulatory Affairs, Medical Affairs, Quality Assurance and Pharmacovigilance. All participants were recognized as regulatory affairs leaders by their stated designation.

b) Is your organization registered with the South African Pharmacy Council?

The total response was “Yes” for 100 % of responses.

The responses indicate that all participating companies were legally registered as pharmaceutical

manufacturers or importers; therefore they were eligible to participate.

c) Do you have an in-house regulatory affairs department?

This received a 78 % for “Yes” and 22 % for “No”.

This question was initially intended to be an exclusion filter, but due to the low number of participants from the Pharmaceutical Industry, this was not applied.

d) Please indicate what type of products are manufactured or imported by your organization.

This question was initially intended to be an exclusion filter for “other” types of products manufactured or imported, but due to the low number of participants from the Pharmaceutical Industry, this was not applied. The responses were however still measured and recorded in Table 4.5 below:

Table 4.5. Types of Products manufactured or imported

Type of Products	Percentage Response	Number of Responses
OTC / Consumer	60 %	30
Generic Medicines	46 %	23
Ethical Prescription Medicines	62 %	31
Other	48 %	24
Total Responses		108

From these results in Table 4.5 it shows that some companies are involved in the manufacture of more than one type of product, therefore the total percentage amounts do not add up to 100. The 48 % of “Other” types of products are comprised of the following listed in Table 4.6 below Once again the percentage responses do not add up to 100 % (Table 4.6) as some of the 24 companies indicated, manufacture more than one type of product. Since these responses were not considered for exclusion criteria, these responses are not directly applicable to the study.

Table 4.6. Types of “Other” Products manufactured or imported

“Other” Type of Product	No. of Responses (out of 24 responses)	Percentage (%) Response
Veterinary / Animal Health	6	25.00
Complementary & Nutritional Supplements	7	29.17
Medical Devices / Dressings	8	33.33
Vaccines	2	8.33
Homeopathic, Section 21, Cosmetics, Herbal Tinctures	4	16.67

4.5 Regulatory Function and Job Description Questionnaire

The second part of the survey (Appendix 2, pages 2-5) was the Regulatory Function and Job Description Questionnaire. This was to assess what kind of regulatory activities each company engaged in. A list of job functions were listed and companies were required to indicate if they engaged in this function by stating “Yes” or “No”.

The responses for this section are summarized in Table 4.7 which indicates that many of the listed job functions are already being carried out by most of the pharmaceutical companies surveyed. Approval of promotional material and competitor challenges (which are related to marketing functions) had lower responses than other functions, at 56 % for each. Responses to the questions relating to other regulatory functions ranged from 74 % to 96 %, indicating that most pharmaceutical companies were engaged in these activities. T-tests were done for all responses, and the sample proportion in most cases was found to be within the 95 % CI, although this was less than the null hypothesis (H_0). The null hypothesis (H_0) is the expected response (indicated as a numerical value of 1 for “Yes”) from companies for engaging in the listed functions. Since most of the sample means are only slightly less than 1 (H_0), it indicates that companies engaged in these functions to a large extent.

4.6 Additional Regulatory Functions

The last question in the job description part of the questionnaire (Appendix 2, page 5) requested for additional regulatory functions which were not listed in Table 4.7, but which the participating companies engaged in. These additional regulatory functions are listed in Table 4.8 below and have been grouped according to the possible departments supported within the company, to simplify the analysis of

responses. The possible departments have been allocated based on the researcher's working experience of 8 years in both quality assurance and regulatory affairs roles. Please refer to the List of Abbreviations on page 9, where relevant.

Table 4.7. Responses to Job Description Questions (1-14)

Question	Yes (%) (n) N=50	No (%) (n) N=50	Proportion	95 % CI Range	H ₀
1. Preparation of medicine registration dossiers for submission to MCC	92 (46)	8 (4)	0.92	0.84 – 1.00	1
2. Preparation of medicine registration dossiers for submission to health authorities out of South Africa (export markets)	82 (41)	18 (9)	0.82	0.71 – 0.93	1
3. Preparation of pharmaceutical amendments of dossiers to submit to MCC (to ensure update of pharmaceutical information in dossier and to ensure Quality Compliance)	96 (48)	4 (2)	0.96	0.90 – 1.02	1
4. Preparation of pharmaceutical amendments of dossiers to submit to health authorities out of South Africa (export markets)	82 (41)	18 (9)	0.82	0.71-0.93	1
5. Preparation of clinical amendments / package insert updates to submit to MCC (to ensure update of clinical information in dossier and to ensure Safety & Efficacy Compliance)	86 (43)	14 (7)	0.86	0.76 – 0.96	1
6. Preparation of clinical amendments / package inserts to submit to health authorities out of South Africa (export markets)	74 (37)	26 (13)	0.74	0.61 – 0.87	1
7. Approval of promotional material for South Africa (Marketing Support)	88 (44)	12 (6)	0.88	0.79 – 0.97	1
8. Approval of promotional material for export markets (Marketing Support)	56 (28)	44 (22)	0.56	0.42 – 0.70	1
9. Submission and approval of labelling and printed packaging updates	94 (47)	6 (3)	0.94	0.87 – 1.00	1
10. Re-registration and licence renewal of products for export markets	76 (38)	24 (12)	0.76	0.64 – 0.88	1
11. Pharmacovigilance support including PSUR's, CCDS and other pharmacovigilance functions	82 (41)	18 (9)	0.82	0.71 – 0.93	1
12. Regulatory intelligence – provide regulatory and or source legal advice when required	84 (42)	16 (8)	0.84	0.73 – 0.95	1
13. Competitor Challenges – co-ordinate the legal process	56 (28)	44 (22)	0.56	0.42 – 0.70	1
14. Engage in and support new launch activities with local, regional and global business	78 (39)	22 (11)	0.78	0.66 – 0.90	1

The 33 listed additional functions (in Table 4.8) not covered in the survey were related to the possible departments depicted in Figure 4.3. Most of these functions are related to Regulatory Affairs and Quality Assurance.

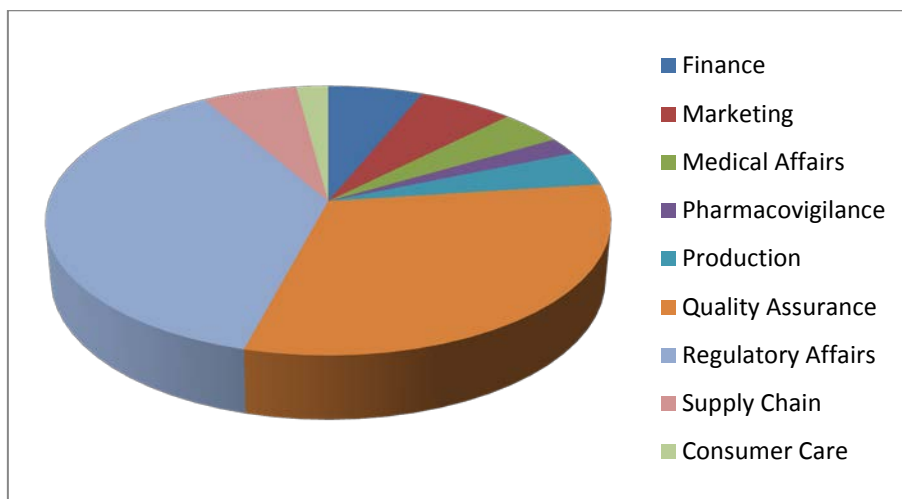


Figure 4.3. Additional Functions and Possible Related Departments

Table 4.8. Additional Regulatory Functions

Details of Additional Functions	No of responses	Possible Department/s Supported
1. Medical Representative technical training and medical field support	1	Marketing
2. Application of permits	1	Supply Chain
3. Writing of SOP's, development and control	2	Quality Assurance, Regulatory Affairs
4. Assisting in price reporting to the pharmaceutical economic evaluation department of Department of Health.	1	Finance
5. Assist in Nappi Code applications	1	Finance, Marketing
6. Audit preparation for MCC and SAPC audits	1	Quality Assurance, Regulatory Affairs
7. Adverse Event reporting to MCC	1	Pharmacovigilance
8. QA function of product release to market	1	Quality Assurance
9. New Business Development: Dossier Screening / due diligence as part of dossier searches	2	Marketing, Regulatory Affairs
10. Providing medical information, literature searches, training and audits	1	Medical Affairs, Regulatory Affairs
11. The main focus of our company is the contract packing of pharmaceutical product and regulatory input deals largely with GMP compliance and licensing issues. We are the applicant for one registered medicine sold in SA only, so all regulatory activities relating to the submission and	1	Quality Assurance, Regulatory Affairs

Details of Additional Functions	No of responses	Possible Department/s Supported
maintenance of a dossier are performed, however pharmacovigilance input is limited		
12. Translations and checking of customer package inserts, PILS and unit cartons	1	Regulatory Affairs
13. Medical Affairs and QA	1	Medical Affairs, Quality Assurance
14. Audit and approval of master manufacturing, packaging, release documents.	1	Production, Quality Assurance
15. Audit and approval of printed material suppliers	1	Quality Assurance
16. Audit and approval of laboratories	1	Quality Assurance
17. Re-ID and assay of imported products and final release	3	Quality Assurance
18. Re-registration and licence renewal of company	1	Regulatory Affairs
19. Attending to telephonic queries on products from customers, reps, general public	1	Regulatory Affairs, Consumer Care
20. Quality aspect is included within our department	1	Quality Assurance
21. We act as FPRR and evaluate retention samples and documentation from all batches before approving release to market	1	Quality Assurance
22. As a third party contractor we closely communicate with the client and advise where possible based on our observations within the industry. We have some 50 clients and we have to remain on top of the latest regulatory requirements and standards. We may not be directly involved with regulatory submissions but actively engage with consultants and client regulatory departments to indirectly maintain and uphold the standards of our profession	1	Regulatory Affairs
23. S6 controlled substances require import permits – application and returns to the Inspectorate; quarterly balancing and annual returns	1	Regulatory Affairs, Quality Assurance
24. Signing off on SEP (Single Exit Price) updates	1	Finance, Marketing
25. Site Master file and all legal entity licence amendments	1	Quality Assurance, Regulatory Affairs
26. Review and sign all technical agreements with GxP 3 rd parties	2	Quality Assurance, Regulatory Affairs
27. Review and sign all GMP: Business Risk Mitigation Plan, Business Continuity Plans	1	Quality Assurance, Regulatory Affairs
28. Third party vendors (printers etc), manufacturers and wholesale audits	1	Quality Assurance
29. Application to MCC for section 21 product authorisations – ordering of such products and release for processing and supply to medical practitioner	1	Regulatory Affairs
30. Veterinary products are registered under Act 36 and not the MCC. Registration requirements are not the same. Being a wholesaler we are not allowed to have our own Act 101/ MCC products	1	N/A
31. Assist factory technical team with guidance around changes	1	Production, Regulatory Affairs

Details of Additional Functions	No of responses	Possible Department/s Supported
required to dossiers (Final Product specifications, process changes etc.)		
32. Application of narcotic permits	1	Regulatory Affairs, Supply Chain
33. Application for import and export permits	1	Regulatory Affairs, Supply Chain

From the results in the job description part of the survey, participants provided additional functions that possibly fell within the scope of some of the departments listed above. This study does not take into account the competency assessment of regulatory affairs personnel in these specified additional functions, only the competency of recent undergraduates for regulatory support functions provided to these departments, as depicted in Table 4.10. This exclusion should be noted during the improvement of regulatory affairs education.

The total number of responses for possible Quality Assurance and Regulatory affairs functions was listed as an additional 16 and 18 respectively. The results indicate that since various types of pharmaceutical companies participated, the possible differences in company structures and department roles may contribute to the additional regulatory affairs functions. This indicates further that the regulatory and quality roles are quite possibly broader than anticipated, especially in smaller pharmaceutical companies with fewer regulatory personnel who manage an array of regulatory activities.

An additional function was noted by the researcher after survey studies were completed. This function was the Application for Exemption from Post-importation testing of final product, specifically for products which are imported and for which transport data has been recorded to show that product has consistently been imported under conditions suitable to maintain the product stability (MCC Guideline, 2.04, 2003). Post importation testing is usually conducted by Quality Control personnel as part of the process to release product for sale, but if exemption is granted by MCC, this may accelerate the rate of release of product for sale. This is a quality related function, but since only regulatory affairs personnel are usually allowed to communicate with MCC, this responsibility may be assigned to regulatory affairs in companies where quality and regulatory roles are separated.

4.7 Regulatory Affairs Leaders

The third part of the questionnaire (Appendix 2, pages 6-8) was to assess the views of regulatory affairs leaders on regulatory affairs education, the significance of the regulatory affairs function within the company, and their experience with recent pharmacy graduates joining the regulatory affairs team. This

part of the questionnaire posed a number of questions and statements with 5 possible response options for each.

The results for this survey are listed as percentages in Table 4.9 below. As with the Pharmacy Schools survey, responses were allocated a numerical value for the purpose of statistical analysis, where strongly agree = 2, agree = 1, neutral = 0, disagree = -1 and strongly disagree = -2.

The responses in Table 4.9 and Figure 4.4 and Figure 4.5 below show various patterns as they address different areas as follows:

Question 1 and 2 and Graphs 1 & 2 in Figure 4.4 indicate that most leaders in regulatory affairs deem regulatory affairs to be an important function in a pharmaceutical company and in the Pharmaceutical Industry, because of the legal role it serves. The responses for “strongly agree” were 82 % and 92 % respectively for Questions 1 & 2.

Question 3 and 4 and Graphs 3 & 4 in Figure 4.4 indicate that regulatory affairs leaders do not perceive regulatory affairs education to be provided at both undergraduate and post-graduate level. The highest number of responses for regulatory affairs being taught at undergraduate level was 44 % in disagreement of this statement.

Question 5 and 6 and Graphs 5 & 6 in Figure 4.4 assessed how regulatory affairs leaders felt education should be structured. The most responses were to “strongly agree” (50 %) that regulatory affairs should be taught as a specialisation subject / module at undergraduate level. There was however a high number of responses (44 %) agreeing that it is better to train regulatory affairs pharmacists fully only once they enter the Pharmaceutical Industry due to the nature of the work. This may not be deemed to be conflicting responses, unless these statements are explored in more depth and can be shown to be conflicting.

Questions 7, 8 and 9 and Graphs 7, 8 & 9 in Figure 4.5 address the overall competence of recent graduates entering the regulatory affairs field. For Question 7, most responses were neutral (36 %) or in disagreement (34 %) that recent graduates were competent for their role. The response for “agree” was 2 % and for strongly agree was 0 %. The responses for Questions 8 & 9 were mostly neutral, possibly because there were two parts to each question providing different reasons for low or no competence, and the reasons for lack of competence wasn’t clear.

Table 4.9. Views of Regulatory Affairs Leaders (1-11)

Question No	Survey question / statement	Strongly agree (2) % (n) N=50	Agree (1) % (n) N=50	Neutral (0) % (n) N=50	Disagree (-1) % (n) N=50	Strongly Disagree (-2) % (n) N=50	Mean	SD
1.	Regulatory Affairs functions are key to a pharmaceutical company as it lays down the basis for all other pharmaceutical functions, and ensures that the company is legally compliant to commence business	82 (41)	18 (9)	0	0	0	1.82	0.39
2.	It is critical for the reputation of the business and the Pharmaceutical Industry that regulatory affairs be given adequate and competent resources to carry out their functions	92 (46)	8 (4)	0	0	0	1.92	0.27
3.	Regulatory affairs functions are taught in Pharmacy Schools at an undergraduate level	10 (5)	14 (7)	16 (8)	44 (22)	16 (8)	-0.42	1.21
4.	Regulatory affairs functions are taught in Pharmacy Schools at a post-graduate level.	8 (4)	16 (8)	50 (25)	22 (11)	4 (2)	0.02	0.94
5.	I suggest that regulatory affairs be taught as a specialization in pharmacy at an undergraduate level, in order to have more competent graduates entering the Pharmaceutical Industry sector.	50 (25)	30 (15)	14 (7)	6 (3)	0	1.24	0.92
6.	It is better to train regulatory affairs pharmacists fully only once they enter the Pharmaceutical Industry due to the nature of the work.	22 (11)	44 (22)	10 (5)	18 (9)	8 (4)	0.5	1.23
7.	Recent graduates (straight out of university), that I employed as regulatory affairs pharmacists were competent for their role.	0	2 (1)	36 (18)	34 (17)	28 (14)	-0.88	0.85
8.	Recent graduates (straight out of varsity) that I employed as regulatory affairs pharmacists were not competent, but were familiar to some degree with regulatory affairs, due to academic learning e.g. intern program	2 (1)	16 (8)	50 (25)	28 (14)	2 (1)	-0.16	0.82
9.	Recent graduates (straight of out varsity), that I employed as regulatory affairs pharmacists were not competent, but were familiar to some degree with regulatory affairs, due to their prior exposure to the Pharmaceutical Industry.	2 (1)	30 (15)	48 (24)	14 (7)	6 (3)	0.08	0.87
10.	I am willing to collaborate with Pharmacy Schools to develop a curriculum for undergraduate students, should there be a need.	24 (12)	32 (16)	38 (19)	6 (3)	0	0.74	0.90

Question No	Survey question / statement	0 to 6 months % (n) N=50	6 to 12 months % (n) N=50	12 to 24 months % (n) N=50	24 to 36 months % (n) N=50	More than 36 months % (n) N=50	Mean	SD
11.	It currently takes on average the following duration for new regulatory affairs pharmacists to become fully competent in their role.	2 (1)	34 (17)	30 (15)	14 (7)	6 (3)	2.04	1.03

This limits the assessment for low competence in this section of the survey; however assessment for competence of graduates is dealt with in more depth in page 49 which deals with the next part of the survey, where the views of leadership can be better assessed. The highest number of ‘strongly disagreeing’ responses was recorded for the statement that recent graduates (straight out of university), employed as regulatory affairs pharmacists were competent for their role. This response was 28 % in disagreement of this statement. The combined ‘disagreeing’ and ‘strongly disagreeing’ responses for Questions 8 & 9 exceeded 50 %, indicating that more than 50 % participants were in disagreement with these statements, overall.

Question 10 & Graph 10 in Figure 4.5 show that the responses on willingness to collaborate with Pharmacy Schools ranged mostly from neutral, to agree and strongly agree. Only 6 % disagreed to collaborate, while 24 % strongly agreed and 32 % agreed to collaborate; 38 % were neutral

Question 11 & Graph 11 in Figure 4.5 show the duration it takes new pharmacists to become fully competent in regulatory affairs. Most responses were 6 to 12 months (34 %) and 12 to 24 months (30 %). This makes it apparent how much time is involved in ensuring that pharmacists reach an acceptable level of competency.

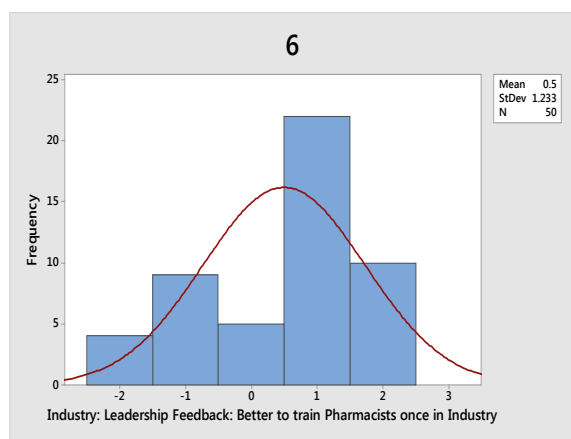
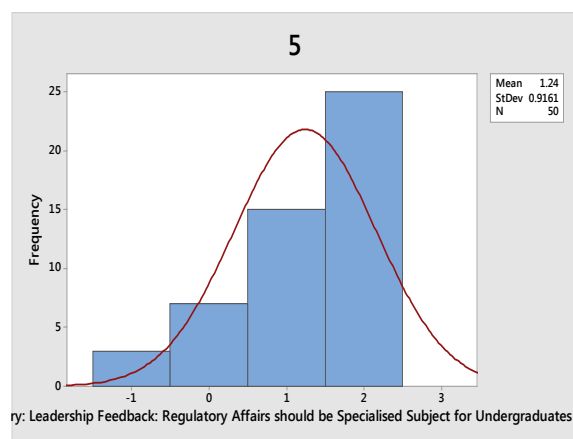
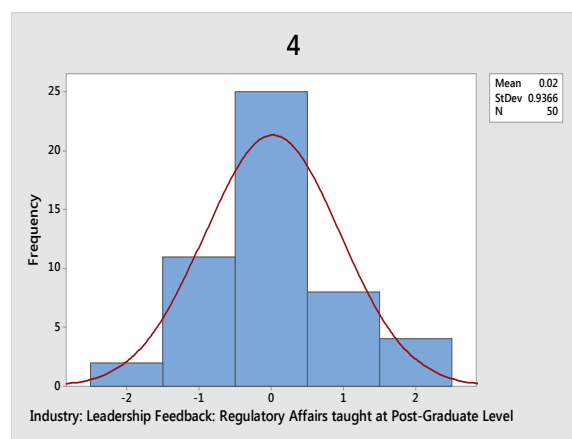
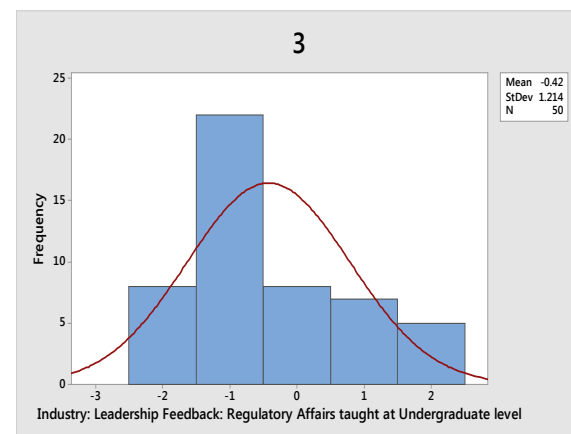
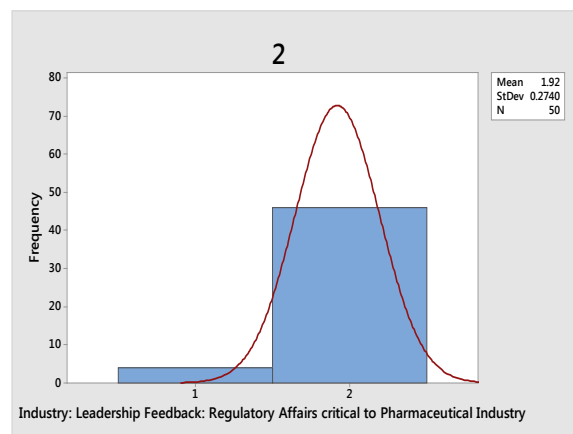
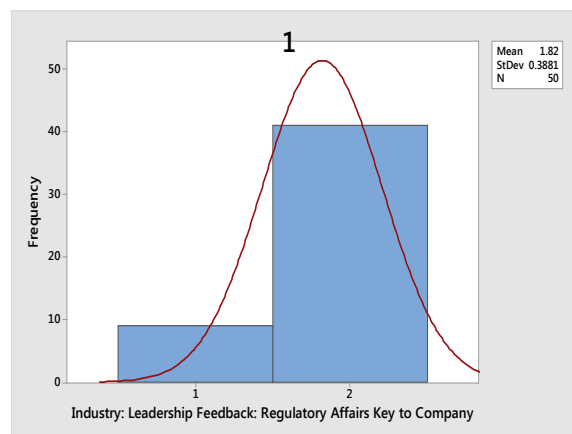


Figure 4.4. Industry - Leadership Feedback (Graphs 1-6)

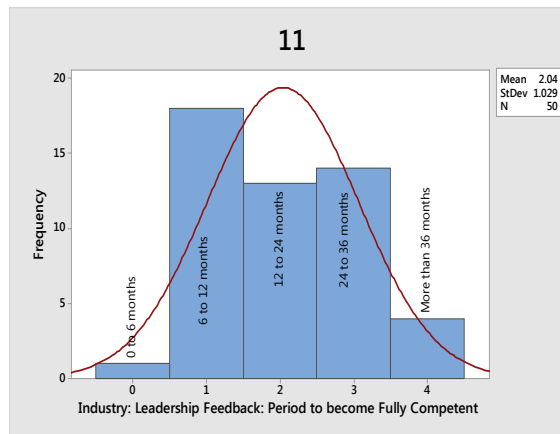
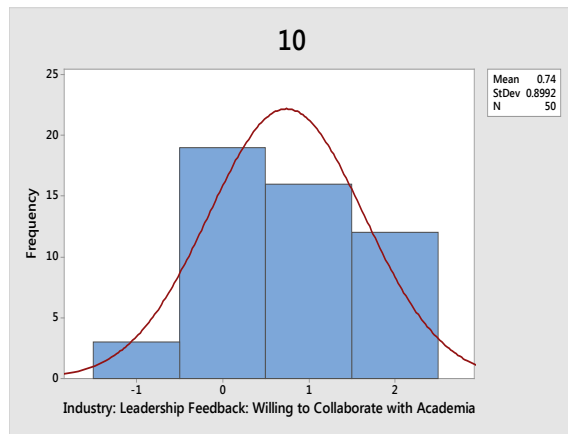
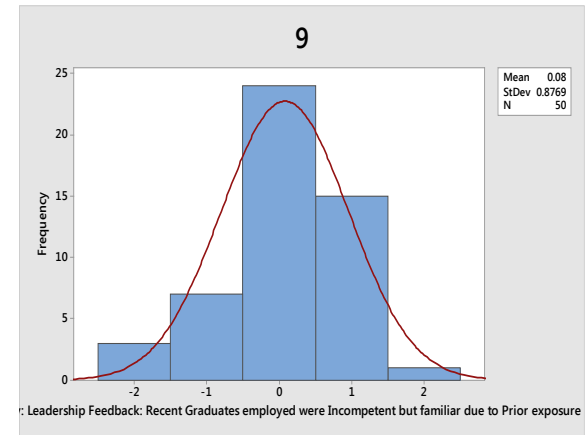
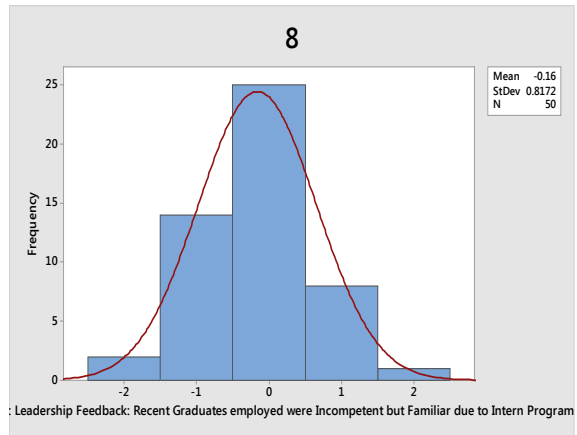
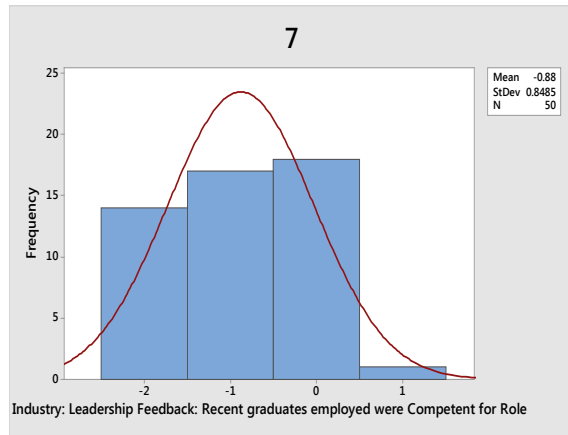


Figure 4.5. Industry - Leadership Feedback (Graphs 7-11)

4.8 Competency of Recent Graduates

The fourth part of the questionnaire (Appendix 2, pages 8-10) related to the competency of recent graduates for the relevant roles in regulatory affairs. Competence was assessed in the general areas within regulatory affairs and cross functional departments where regulatory support is needed, and not only according to the specified job functions covered in the first part of the survey (Table 4.7). This was done to obtain a broad overall competency assessment both within the regulatory affairs department and the cross-functional support that they provide to other departments. The results are indicated below in Table 4.10 in percentages. For the purposes of statistical analysis, responses were allocated a numerical value where mostly competent =1, mostly incompetent = -1 and not applicable = 0.

Table 4.10. Competency of Recent Graduates (1-8)

Regulatory Function	Mostly Competent (1) % (n) N = 50	Mostly Incompetent (-1) % (n) N = 50	Not applicable (0) % (n) N = 50	Mean	SD
1. Knowledge of Pharmacy Legislation	48 (24)	30 (15)	22 (11)	0.18	0.87
2. Dossier Compilation	2 (1)	74 (37)	24 (12)	-0.72	0.50
3. Production Support	12 (6)	56 (28)	32 (16)	-0.44	0.70
4. Supply Chain Support	12 (6)	50 (25)	38 (19)	-0.38	0.70
5. Quality Assurance Support	20 (10)	54 (27)	26 (13)	-0.34	0.80
6. Marketing Support	10 (5)	56 (28)	34 (17)	-0.46	0.68
7. Pharmaceutical Knowledge	60 (30)	16 (8)	24 (12)	0.44	0.76
8. Clinical Knowledge	48 (24)	26 (13)	26 (13)	0.22	0.84

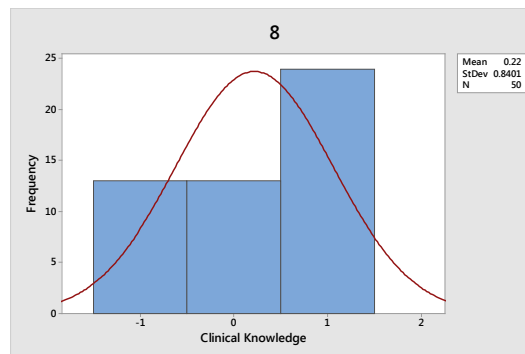
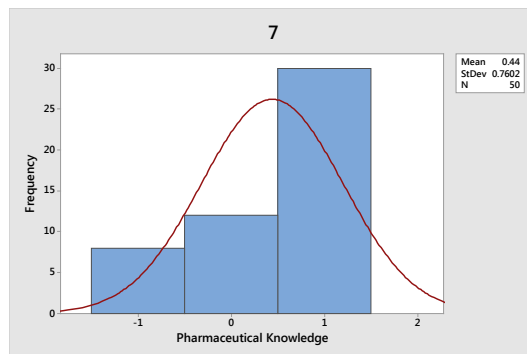
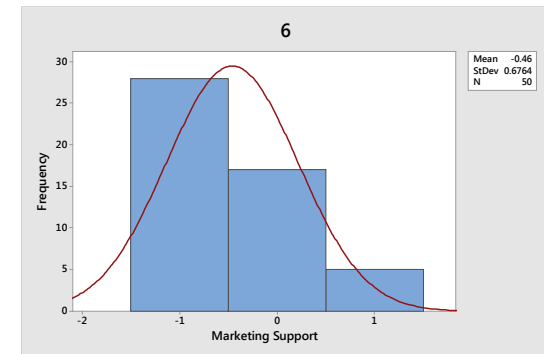
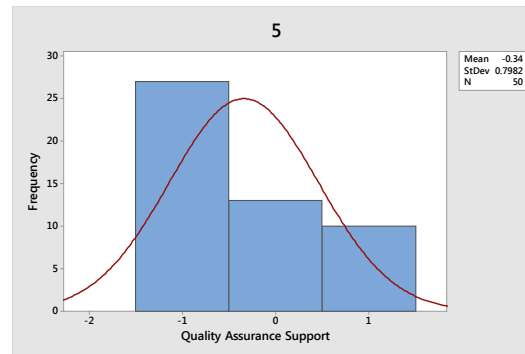
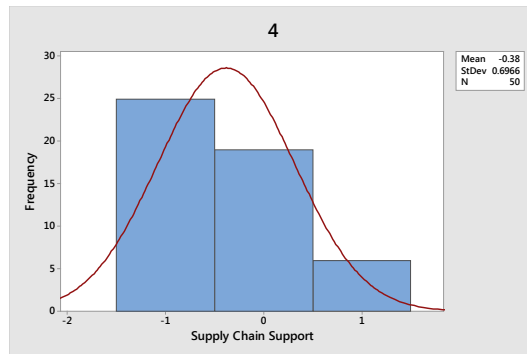
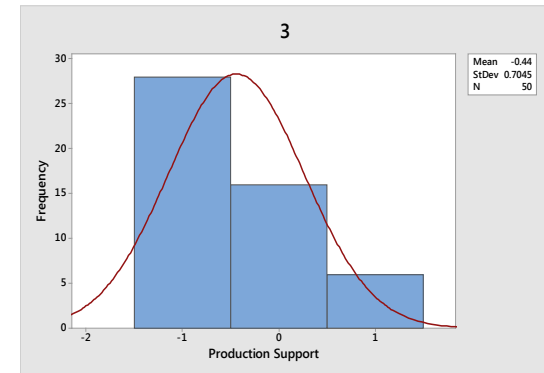
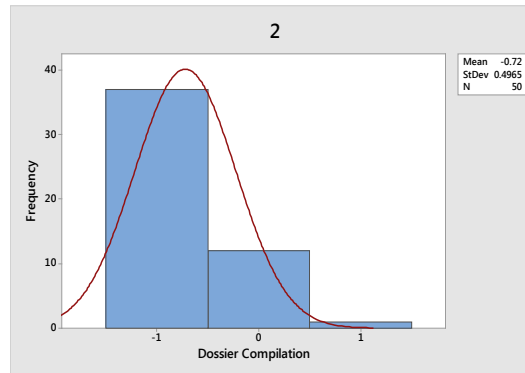
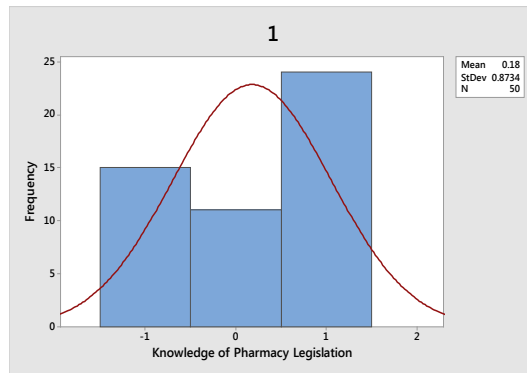


Figure 4.6. Competency of Recent Graduates (Graphs 1-8)

The responses shown in Table 4.10 and Figure 4.6 vary. Responses for most of the areas assessed indicate that recent graduates were mostly incompetent, except for Knowledge of Pharmacy Legislation, Pharmaceutical Knowledge and Clinical Knowledge. This stands to reason as these are key areas covered in the current Pharmacy School curricula (Pharmacy Act, 2002), which are further detailed on page 14. Key areas which require extensive regulatory knowledge which produced “mostly incompetent” responses were for dossier compilation, production support, supply chain support, quality assurance support and marketing support. The mean for these responses were less than 1, indicating that no regulatory function which was assessed (excluding the ‘knowledge’ questions), produced a result of “mostly competent”. These are the areas which should be considered for inclusion into the undergraduate B. Pharm curricula, in further consultation with the requirements of The Medicines Act (Act 101 of 1965) as detailed on on page 15, and with the various MCC Guidelines.

4.9 Additional Open Text Comments

Additional “open text” comments were invited by participants with regard to competency of recent graduates. Please refer to List of Abbreviations on page 9, where relevant.

Their verbatim responses were as follows:

1. “In general recent graduates have displayed an overwhelming interest for entry into this sector, but combined with a very superficial understanding of the type of work done in this field and the type of personality / character best suited to this type of work”
2. “Because we make use of contracted regulatory pharmacists, it is not easy to answer some of these questions from experience. It will be beneficial to be able to do a post-graduate course if you wish to enter that specialized field in pharmacy”
3. “We have started our own graduate program in training 3 pharmacists / scientists in regulatory affairs over a 12 month period for three years”
4. “Poor organization skills”
5. “I do not have experience with recent graduates as I am the only pharmacist in the company – would like to have training for myself on the correct and maybe easier way of doing regulatory work. Not sure if regulatory forms part of the curriculum, in my years it didn’t”
6. “Completion of ZA CTD’s” (CTD = Common Technical Document / Dossier)
7. “Note: Marked N/A as currently do not employ recent graduates. This may skew the answers on previous page. I have therefore offered an opinion on the previous page”
8. “N/A”

9. "Not applicable to me, as we do not have any other pharmacists employed.
10. "1. Writing and compilation of SOP's – incompetent. 2. Writing of business letters – incompetent. 3. Customer complaints and product recall – competent. 4. Annual Product Review – incompetent. 5. CAPA – incompetent. 6. Document control 50/50" (CAPA = Corrective and Preventative Action)
11. "We haven't employed anyone just out of university therefore difficult for me to comment"
12. "One of the key areas critical to regulatory affairs is the ability to communicate confidently at different levels internally and externally, with business stakeholders and regulatory authorities, in a language that they understand. This is an area that most graduates underperform in as their communication skills – oral, written and verbal, is usually very underdeveloped"

Of the twelve responses received, 4 responses related directly to the question, 4 responses related indirectly to the question and 4 responses were to advise that recent graduates or other pharmacists were not employed for various reasons. The comments related directly to the question were summarized as follows; soft skills such as organization skills and communication skills (oral, written and verbal) were cited as important skills which were lacking in recent graduates; some functional areas where competency could be improved is in "completion of ZA CTD's, writing and compilation of SOP's, writing of business letters, annual product reviews, CAPA and document control."

Responses related indirectly to the question were statements that recent graduates did not have an understanding of the right type of personality suited to the type of work. One participant expressed a need to have training for him or herself on the correct and easier way of working in regulatory affairs. One company has started a graduate program to train 3 pharmacists / scientists in regulatory affairs over a 12 month period, for 3 years. Another participant felt that it would be beneficial to do a post-graduate course to enter this specialised field in pharmacy.

4.10 Suggestions for Future Regulatory Affairs Module in B.Pharm Degree

The last part (Appendix 2, page 10) of the survey invited participants to make suggestions for areas in regulatory affairs practices to be included in a future regulatory affairs module of the B. Pharm undergraduate curriculum. This is listed verbatim as follows:

1. "It should be part of specialisation as is hospital pharmacy vs retail vs clinical vs production and QA." (QA = Quality Assurance)
2. "Modules providing details on the technical aspects of the dossier are required so that the

regulatory affairs pharmacist can access whether the information received from the various departments are acceptable. e.g. - train up the RA in drawing up of raw material specifications, final product specifications, requirements of analytical method validations etc.”

3. “eCTD” (eCTD = electronic Common Technical Document)
4. “Pharmacovigilance, Basic CTD compilation and CMC writing skills” (CMC = Chemistry, Manufacturing, Controls)
5. “More detail regarding amendments to the Dossiers, as this is what is put into practice at manufacturing sites”
6. “Completion of ZACTD's, Analytical, Stability” (ZACTD = South African CTD)
7. a). “Knowledge of pharmaceutical production, including manufacturing processes and relevant equipment used.”
b). “Document control - including Change Control and Handling of Deviations.”
c). “CAPA - Corrective and Preventative Action”
d). “Annual Product Review - how to set up a template/system/SOP to investigate products.” (SOP = Standard Operating Procedure)
e). “How to write an SOP/Working document” (SOP = Standard Operating Procedure)
f). “How to compile a Batch Manufacturing & Batch Packaging document”
g). “Validation & Qualification of Processes, Equipment & Systems.”
h). “Study the "Guide to GMP for Medicines in South Africa" - guidelines by the MCC.(this covers all the points I've mentioned here).” (GMP = Good Manufacturing Practices)
i). “Quality Risk Management”
j). “How to conduct a self-inspection/audit, including writing up of SOP covering this, and development of a template.”
k). “Technical Agreements”
l). “Review of PIC/S and other internationally-recognised regulatory bodies.”(PICS = Pharmaceutical Inspection Cooperation Scheme).
8. “It is very specialised and so much detail.”
9. “Introducing a module in regulatory affairs during undergrad. will not even give a "taste" to an upcoming pharmacist as to what a regulatory affairs pharmacist does. There should be an option in varsity to study a further 1 year (post-grad) to get a decent grasp of what it

takes to be a regulatory affairs pharmacist either by the university entering into partnerships or directly corresponding with the regulatory authority. This will also help to improve the skills levels in the regulatory authority if they have candidates who are experienced in this field available rather than developing their own in-house which can take 12-24 months by which time industry snaps them up.”

“However, after the 1 year post-grad there should be job opportunities available, which isn't the outcome currently due to restrictive labour conditions and also importation of generics from other countries, making it extremely difficult for SA companies to compete. A country like China (for eg.) can produce the same medicine in China at half the cost of what it costs to produce in SA.”

10. “I don't know the current B.Pharm undergraduate curriculum and what aspects of current regulatory affairs is covers, thus not able to make suggestions”
11. “I strongly agree that regulatory affairs should be considered as an elective subject, outlining the basis for doing a dossier screening and compilation.”
12. “The students should be given a detailed overview of the RA function within the Pharmaceutical Industry.” (RA = Regulatory Affairs)
13. “Communication skills - the ability to communicate persuasively to stakeholders you have no authority over.”
14. “If someone is interested in following a career in regulatory affairs (and it is NOT for everyone - very special skills are required) they must be exposed to the Medicines and Related Substances Control Act, Act 101 of 1965 as amended, the regulations thereto and most importantly to all the relevant guidelines extensively. Practical experience in applying the above mentioned guidelines, in my opinion, is imperative.”
15. “Suggest in final year for a short course (6 months) elective in Regulatory Affairs (as offered previously/currently by Rhodes) cannot take away from the fact that community service places a 'regulatory' only specialised pharmacist at a disadvantage for practice. Otherwise offer as post-grad courses, the whole Pharmacy undergrad ultimately already contributes to a well-rounded reg affairs pharmacist, then need to specialize.”
16. “Pharmacovigilance is quickly becoming top priority not only for Multi Nationals but also generic companies. A shortage of expertise exists in this area. The proposed module should definitely include this area of learning. ”
17. “Dossier compilation and the skills required to evaluate information for inclusion into a

registration dossier. Dossiers come through the department that are sloppy and the information is not sufficient / inappropriate. Learn how to basically communicate with the MCC and Department of Health.”

18. 1. “The Pharmacy Act”

2. “Medicines and related substances, Act 101”

3. “CTD brief introduction”

4. “Correlation between how products start out, their life cycle through preclinical & clinical stages, dossier compilation.”

5. “The link between CTD parts and working master documentation for the product.”

19. “My understanding is that the Act is covered, and basic dossier structure requirements may be covered, but a much greater depth in the understanding of MCC guidelines for medicine registration is sorely lacking. The process involved in respect of interaction and actual responsibilities in respect of all other areas of the business should be addressed in much greater detail, such that the candidate is competent in writing SOPs, reports and other technical documents, is familiar with how to release/support the release of product, understands the requirements for artwork and marketing material approval, all over and above being able to understand how to scientifically and technically assess and compile a dossier for submission to the South African regulatory authorities. Another very important skill, often lacking are computer skills and/or IT savvy, around the importance of electronic document control and storage. IT organisational skills are critical, and so often sorely lacking in recent graduates, and ideally should be taught within the curriculum as an essential skill. Kitting new regulatory pharmacists with the added skill of being able to work in a paper-less environment is also a challenge for the current to new future.”

20. “I think it should be added as an extra course for those wishing to pursue this as a career and not for all pharmacists who will maybe enter retail or purely clinical work”

These suggestions are further discussed in Chapter 5.2.

5 CHAPTER 5: DISCUSSION AND RECOMMENDATIONS

5.1 Pharmacy School and Pharmaceutical Industry Results

The aim of this study was to assess if there are inconsistencies in regulatory affairs between the pharmacy curriculum and job descriptions of regulatory affairs pharmacists, and to determine if graduating pharmacists entering industrial pharmacy are equipped for their role in regulatory affairs. The objectives were to compare regulatory education and industrial practices to assess deficiencies in the required competencies of a regulatory affairs pharmacist. The appropriate sections in the Pharmacy curricula from all eight Pharmacy Schools in South Africa were examined to assess the level to which regulatory affairs is taught and job descriptions of regulatory affairs pharmacists were examined to assess the functional competencies required. The aim and objectives were achieved as shown clearly by the results; in South Africa pharmacists who are seeking a career in regulatory affairs are not adequately prepared for their role after they graduate from university with a B.Pharm degree.

In the survey to Pharmacy Schools, the results in Table 4.1 indicate that Pharmacy School participants were fairly well equipped with a basic knowledge of regulatory affairs. Pharmacy Schools have noted that there is a lack of a regulatory affairs module at undergraduate level and have made amends to include this at a post-graduate level. In the survey to pharmacy schools, copies of the undergraduate curriculum for the Pharmacy Practice course from 1st year to 4th year were requested. This may have limited the study since regulatory affairs may be taught in other courses at undergraduate level. Regulatory education is considered to be covered only partially at undergraduate level, but taught more specifically and holistically at post-graduate level, in most Pharmacy schools (see page 33). Some schools include medicine registration as part of the compulsory undergraduate curriculum or as an elective subject / project in the final year of the B.Pharm curricula. The post-graduate courses in regulatory affairs are offered by most schools, but it is not known how many graduating pharmacists pursue this option before embarking on a career in regulatory affairs.

For the survey to the Pharmaceutical Industry, the total number of pharmaceutical companies registered with the SAPC, for which valid email addresses were available are 254; therefore this was the maximum number eligible to participate in this survey, hence the sample size was limited. The sample size required to provide a confidence interval (CI) of 95 % with a significance level (p-value) of 0.5 was 185. Since only 50 responses were received, the CI

obtained with this sample size was 47 % for a significance level of 0.5. This has been a limiting factor to this study for all responses received from Pharmaceutical Industry participants.

The results from the survey to the Pharmaceutical Industry showed that the job functions listed under the job description were practised by most companies, and these were in keeping with the requirements of the Medicines Act and the MCC Guidelines (refer to pages 12, 15 and 18). The sample means for most questions were only slightly less than the null hypothesis (H_0) of 1, therefore indicating that companies engaged in these functions to a large extent (see page 39).

Although some aspects of regulatory affairs, such as medicine registration is included in the curricula of the B.Pharm degree in some schools, regulatory affairs leaders in industry still deem recent graduates to be insufficiently competent when they are employed. The survey assessing the competency of undergraduates showed that recent graduates were mostly competent in Knowledge of Pharmacy Legislation, Pharmaceutical Knowledge and Clinical Knowledge. This is expected as these areas are covered in the current Pharmacy School curricula (Pharmacy Act, 2002), which are further detailed on page 14. The areas which should be considered for inclusion into the undergraduate B. Pharm curricula are dossier compilation, production support, supply chain support, quality assurance support and marketing support. This should be done in further consultation with the requirements of The Medicines Act (Act 101 of 1965) and with the various MCC Guidelines to understand the detail of these roles.

This study also shows that the scope of regulatory work is quite broad and supports a number of other functional areas such as manufacturing, quality assurance, marketing and supply chain (see Table 4.8). The assessment of competencies required for this kind of broad role was not covered in this study, and should be examined in more detail.

In the survey to Regulatory Affairs leaders (see page 43) there were two questions (8 and 9) and Graphs 8 & 9 in Figure 4.5 which addressed the overall competence of recent graduates entering the regulatory affairs field. The responses for Questions 8 & 9 were mostly neutral, possibly because there were two parts to each question providing different reasons for low or no competence, and the reasons for lack of competence wasn't clear. This limits the assessment for competence in this section of the survey, and the interpretations of these responses should be explored further.

5.2 Suggestions for a Future Regulatory Affairs Module

The last part of the survey to the Pharmaceutical Industry requested for suggestions for a future regulatory affairs module in the B.Pharm degree (See Chapter 4.10). Twenty participants provided an array of responses; these are discussed as follows with some additional comments by the researcher based on 8 years' experience in the pharmaceutical industry:

- Some felt that Regulatory affairs should be taught as a specialisation but that this should be done as an additional year of study after the normal B.Pharm degree has been completed. This should be an option only as some pharmacists may want to pursue careers in other areas of pharmacy such as retail or purely clinical work. Job opportunities in regulatory affairs should then be made available soon after; however it was noted that the current labour situation and compulsory community service may put a specialised “regulatory” pharmacist at a disadvantage since community service is only done at public hospitals. This option therefore requires broader considerations which are beyond the scope of this study.
- Some felt that regulatory affairs should be done in the fourth year of study as an elective subject for at least six months. From the Pharmacy School survey, it is clear that this is currently being included in the curricula of some Pharmacy Schools.
- Some felt that more emphasis should be placed on equipping students with the relevant legislations such as the Pharmacy Act and Medicines and Related Substances Control Act as amended, with their regulations, as well as an in depth understanding of the MCC Guidelines and practical application of them. This is an important consideration as the Medicines Act, and in particular the MCC Guidelines (which are based on the Medicines Act, and which are regularly updated) provide clear guidance of the regulatory activities and procedures required in industry.
- Others felt that product life-cycle throughout the preclinical and clinical stages to dossier compilation should be included. Product life-cycle covers various topics, which refer to the different types of amendments which could be made before and after registration of the product. These are described in the MCC Amendments Guideline (MCC Guideline 2.08, 2012) and the MCC General Guideline (MCC Guideline 2.01, 2012).

- Some were keen to see knowledge of pharmaceutical manufacturing process and relevant equipment included. Some expressed the need to include manufacturing documents such as batch manufacturing and batch packaging master documentation. These documents are controlled by Production and Quality Assurance but an understanding of the content may benefit regulatory affairs pharmacists when preparing dossier registrations and amendments.
- Many participants expressed a strong need to have modules which trained students to be more competent in the CTD documentation in the dossier as well as the master documentation linked to the CTD compilation. Dossier compilation and the skills required to evaluate information for inclusion into a registration dossier was also cited as being important to include. The MCC Guidelines go into much depth with regards to CTD compilations, which should be included into the curriculum (MCC Guideline 2.24, 2012).
- Some felt that amendments to dossiers and CMC (Chemistry, Manufacturing and Controls) writing skills should be addressed. This includes (but is not limited to) raw material specifications, final product specifications, analytical method validations, analytical procedures and stability data. These form part of the technical parts of the dossier, are written during Product Development (before registration) and updated by designated personnel after registration. Regulatory affairs pharmacists should have a good understanding of what this entails in order to ensure that this is correctly compiled for product registration and to assess the impact to the dossier when an amendment is required. The specific requirements for these parts in the dossier, for the relevant amendments, are covered in the MCC Amendment Guideline (MCC Guideline 2.08, 2012).
- Some quality assurance related areas such as document control including change control and handling of deviations were also suggested. Other quality related areas mentioned were Audit CAPA's (Corrective and Preventative Action); annual product reviews; SOP writing; validation and qualification of processes, equipment and systems; quality risk management; conducting self-inspections / audits and competence in GMP (Good Manufacturing Practice) Guidelines. Although these are predominantly quality related activities, regulatory affairs is quite involved in these areas, and therefore it is important to understand these activities.

- The need to be more competent in Pharmacovigilance requirements was cited, since this is becoming more of a priority for both generic and ethical medicine companies. It was noted that Technical agreements (with third parties) should be included as well. The requirements to monitor safety and efficacy of medicines before and after registration are detailed in the MCC Guidelines (MCC Guideline 2.33, 2012), and regulatory affairs pharmacists will greatly benefit from understanding how regulatory activities contribute to this.
- Other areas to include were computer skills for electronic document control and management. As the regulatory environment quickly becomes more paperless this will become a more important skill to have. Currently the challenge is to not only equip pharmacists with regulatory knowledge but also advanced computer skills. It is not known to what extent computer literacy studies are covered by the various pharmacy schools during the undergraduate curriculum; this should be assessed further as more developments are made towards electronic documentation.
- Communication and influencing skills specifically for persuasive communication with regulatory agencies were cited in this section, emphasizing the need to teach more soft skills. Regulatory affairs involves much interaction with internal and external stakeholders; having the required communication and influencing skills are imperative to enforcing regulatory practices within the organisation and in obtaining the required outcome from external interactions with health authorities, trade associations and regional partners.

These suggestions could be useful in developing more comprehensive programs for regulatory affairs training at undergraduate and post-graduate level. Many of these suggestions can be linked to the published MCC Guidelines, which describe the regulatory requirements in more detail. These may be found on the MCC website, <http://www.mccza.com/Publications/Index/1>. The overall suggestion is that pharmacy schools examine the current MCC Guidelines to understand the theory of specific regulatory requirements and procedures, and collaborate with industry to get a better context of how these may be applied in practice.

5.3 Recommendations for Collaboration between Academia and Industry

Most participants from Pharmacy Schools and the Pharmaceutical Industry indicated their willingness to collaborate with each other to improve the curriculum of the undergraduate degree. There is some disjointedness in what happens to students once they graduate and their potential to be employed in the regulatory profession. Partnering between academia and industry will address this disconnection to provide employers and students with a platform to respectively offer and receive the required knowledge, experiences and opportunities (Robinson, 2006).

Collaboration between academia and industry has been explored in India, Australia and the UK, and has been shown to be of benefit to both students and the Pharmaceutical Industry (Khar, et al., 2011); (Report on Skills Gap, 2007); (Stanley, et al., 2005). This kind of collaboration in South Africa will also elucidate the gaps in pharmacy education and help to determine more conclusively if and how the B.Pharm curricula can be improved, or if regulatory affairs should be a focus at post-graduate level. It is not clear what collaboration platforms are feasible for South Africa; some opportunities which were cited in a study done in Australia (Report on Skills Gap, 2007), and which have been included in Chapter 2.8, may be explored further for use in a South African context.

6 CHAPTER 6: CONCLUSION

The aim and objectives of this study were achieved. The B.Pharm curricula of all Pharmacy Schools were examined, together with post-graduate courses and other courses that they offered. Job descriptions of regulatory affairs pharmacists were assessed to determine the functional competencies that are required. Current regulatory education and industrial practices were compared with each other and many deficiencies in education were identified by regulatory affairs leaders, to meet the objectives of this study. The key reason that the pharmacy curricula at undergraduate level does not adequately cover regulatory affairs education is because the pharmacy curricula is based on the seven unit standards prescribed for pharmacy education, and is published in the Pharmacy Act 53 of 1974 (Pharmacy Act, 2002). Regulatory affairs practices in industry are however established by the Medicines and Related Substances Control Act 101 of 1965 (Medicines Act, 2002).

The results of this study show that graduating pharmacists, entering the Pharmaceutical Industry are insufficiently equipped for their role in regulatory affairs. Suggestions were invited from Pharmacy Schools and the Pharmaceutical Industry for a future regulatory affairs module in the B.Pharm curriculum. Most suggestions which were received from the Pharmaceutical Industry were in line with published MCC Guidelines, which are based on the Medicines and Related Substances Control Act 101 of 1965. The recommendation is that pharmacy schools review the current published MCC Guidelines to understand the theoretical scope of regulatory affairs practices in the Pharmaceutical Industry. Collaboration between academia and industry is further encouraged to understand how these guidelines may be applied in regulatory practices for the different types of medicines manufactured. Pharmacy Schools and Pharmaceutical companies indicated an interest in this kind of collaboration. Collaboration between academia and industry in the health sector has been shown to be beneficial in other countries, and is expected to produce favourable results if embarked upon in South Africa.

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1 APPENDICES

Appendix 1: Letter and Survey to Pharmacy School

Department of Pharmacy and Pharmacology - University of Witwatersrand - Regulatory Affairs Education Questionnaire

Dear Head of Pharmacy School

I am a postgraduate student at the University of the Witwatersrand currently studying towards an MSc.Med degree in Pharmacotherapy. As part of my studies, I am required to complete a research project. My research topic is "Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists". This topic entails examining the current undergraduate curriculum in all pharmacy schools in South Africa in order to determine the extent to which regulatory affairs is taught.

As head of a pharmacy school, you have been invited to participate in this study by completing a short questionnaire. Please note that all information provided will be kept in strict confidence for use by myself and my supervisors for the sole purpose of this study. No information will be disclosed to any other persons or entities. At the end of the study, upon your request we will forward you the results of the outcome and any recommendations that could be made to complement your curriculum.

Please could you kindly complete and submit this questionnaire as soon as is convenient for you. My deadline for collating this information is the 31st October 2014. My e-mail address is Marlene.Moonsamy@students.wits.ac.za.

Please click on the weblink at the top of the page to be directed to the survey.

Many thanks for your kind co-operation.

Yours faithfully

Marlene Moonsamy (082-321-1789) - Student

Mrs N. Padayachee (084-230-2364) - Supervisor

Assoc. Prof. R. van Zyl (083-312-0228) - Supervisor

* Required

Basic Information

Please complete the following basic information before continuing with the questionnaire

1. Date: *

Please select the date of completion of this questionnaire below.

.....
Example: December 15, 2012

2. Designation of Person Completing Questionnaire *

Please enter your designation in the space below

3. Name of Pharmacy School *

Please enter the name of your Pharmacy School in the space below

Pharmacy School Curriculum Questionnaire

Thank you for choosing to participate in this study. The following questions are based on your role in coordinating the curriculum for pharmacy students.

4. I am familiar with the concept of "regulatory affairs" in pharmaceutical industry *

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

5. I am familiar with the requirements of regulatory affairs in industry *

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

6. I am familiar with the various ACTS (legislation) governing regulatory practice in South Africa.

*

Choose one option below that best describes your choice

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

7. I am familiar with the different and changing FORMATS of the registration dossier viz. MBR1, MRF, CTD, eCTD. *

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

8. I am familiar with the CONTENT of the registration dossier for the various formats - MBR1, MRF, CTD, eCTD.

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

9. I understand the role and functions of the MCC (Medicines Control Council) *

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

10. I am familiar with the guidelines published by the MCC *

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

11. I am familiar with the various trade associations, which exist to support the pharmaceutical industry in SA, including SAPRAA (South African Pharmaceutical Regulatory Affairs Association). *

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

12. I am familiar with the SA Marketing Code of Practice, which describes the regulations for the advertising of medicines in South Africa. *

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

13. I am aware of the need for pharmacy students in South Africa to be well equipped in regulatory affairs functions by the time they graduate. *

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

14. **The undergraduate B.Pharm curriculum at this Pharmacy School consists of a regulatory affairs module, which covers the main requirements of regulatory functions. ***

Choose one option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

15. **This Pharmacy School provides regulatory affairs education at a post-graduate level. ***

Choose one option below that best describes your response

Mark only one oval.

- ☐ yes
- ☐ no
- ☐ don't know

16. **This Pharmacy School is willing to collaborate with the pharmaceutical industry and trade associations to develop a curriculum for regulatory affairs, should there be a need. ***

Choose one option below that best describes your response

Mark only one oval.

- ☐ yes
- ☐ no
- ☐ don't know

17. **Please provide details of content and duration of subjects covered in the Pharmacy Practice (or similar) module of the B.Pharm degree from 1st year to 4th year, alternatively material/course outline may be emailed to marlene.moonsamy@students.wits.ac.za to be collated by investigator. ***

A text box is provided below for a detailed description.

18. **If regulatory affairs education is covered in any other module or course (including post graduate courses), kindly indicate this and provide the subjects for that particular module or course, alternatively material/course outline may be emailed to marlene.moonsamy@students.wits.ac.za to be collated by investigator.**

A text box is provided below for a detailed explanation

19. **Please make suggestions (if any) for areas in regulatory affairs practices to be included in a future regulatory affairs module of the B. Pharm undergraduate curriculum:**

A text box is provided below for any insights you may wish to share

20. **Should you wish to be informed of the outcome of this study, please provide your email address in the space below**

Appendix 2: Letter and Survey to Pharmaceutical Industry

Department of Pharmacy and Pharmacology - University of Witwatersrand - Regulatory Affairs Education Questionnaire

Dear Responsible Pharmacist

I am a postgraduate student at the university of the Witwatersrand, currently studying towards an MSc.Med degree in Pharmacotherapy. As part of my studies, I am required to complete a research project. My research topic is "Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists"

This topic entails examining job descriptions of regulatory pharmacists in various pharmaceutical companies in South Africa, in order to determine the level of expertise required to perform Regulatory affairs functions.

I would be grateful for your contribution to this study by indicating key regulatory functions which are practiced and comprised in the job description of regulatory affairs pharmacists in your organization and by completing the short questions which follow to further contribute to the outcome of this study.

Please note that all information provided will be kept in strict confidence for use by my supervisors and myself for the sole purpose of this study. No information will be disclosed to any other persons or entities.

At the end of the study, upon your request we will forward you the results of the outcome and any recommendations that could be made to complement current regulatory affairs practices in industry.

Please could you kindly return responses to this questionnaire to me as soon as is convenient for you. My deadline for collating this information is the 31st October 2014. My e-mail address is Marlene.Moonsamy@students.wits.ac.za.

Please click on the weblink at the top of the page to be directed to the survey.

I look forward to your kind co-operation in this study.

Yours faithfully

Marlene Moonsamy (082-321-1789) - Student

Mrs. N. Padayachee (084-230-2364) - Supervisor

Assoc. Prof. R. van Zyl (083-312-0228) - Supervisor

* Required

Basic Information

Please complete the following basic information before commencing with the questionnaire.

1. Date *

Please insert the date of completion of this questionnaire in the space below

.....
Example: December 15, 2012

2. Designation of Person completing questionnaire *

Please insert your designation in the space below and specify if this includes the role of "Responsible Pharmacist"

.....
.....
.....
.....
.....

3. Is your organisation registered with the South African Pharmacy Council *

Please tick one of the check boxes below which apply

Check all that apply.

☐ yes

☐ no

4. Do you have an in-house regulatory affairs department? *

Please tick one of the check boxes below which apply

Check all that apply.

☐ yes

☐ no

5. Please indicate what type of products are manufactured and or imported by your organisation *

Please choose all options that are applicable

Check all that apply.

☐ OTC / Consumer

☐ Generic Medicines

☐ Ethical Prescription Medicines

☐ Other

6. If you chose "Other" in the above question, describe the type of products manufactured and or imported by your organisation

Please insert your description in the box below

Regulatory Function and Job Description Questionnaire

Please tick either "yes" or "no" for the options listed below to indicate key regulatory functions which are practiced and comprised in the job description of regulatory affairs pharmacists in your organization.

7. **Preparation of medicine registration dossiers for submission to MCC. ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

8. **Preparation of medicine registration dossiers for submission to health authorities out of South Africa (export markets). ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

9. **Preparation of pharmaceutical amendments of dossiers to submit to MCC (to ensure update of pharmaceutical information in dossier and ensure Quality compliance) ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

10. **Preparation of pharmaceutical amendments of dossiers to submit to health authorities out of South Africa (export markets) ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

11. **Preparation of clinical amendments / package insert updates to submit to MCC (to ensure update of clinical information in dossier and to ensure Safety & Efficacy compliance) ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

12. **Preparation of clinical amendments / package insert updates to submit to health authorities out of South Africa (export markets) ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

13. **Approval of Promotional Material for South Africa (Marketing Support) ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

14. **Approval of Promotional Material for export markets (Marketing Support) ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

15. **Submission and approval of labelling and printed packaging updates. ***

Please choose one option below

Check all that apply.

☐ yes

☐ no

16. **Re-registration and licence renewal of products for export markets ***

Please choose one option

Check all that apply.

☐ yes

☐ no

17. Pharmacovigilance support including PSUR's, CCDS and other pharmacovigilance functions *

Please choose one option below

Check all that apply.☐ yes☐ no**18. Regulatory Intelligence – provide regulatory and/or source legal advice when required. ***

Please choose one option below

Check all that apply.☐ yes☐ no**19. Competitor Challenges (co-ordinate the legal process) ***

Please choose one option

Check all that apply.☐ yes☐ no**20. Engage in and support new product launch activities with local, regional and global business. ***

Please choose one option

Check all that apply.☐ yes☐ no**21. Please add any additional regulatory functions not listed above which your organisation engages in.**

Please describe these functions briefly in the space provided below.

Regulatory Affairs Leadership Questionnaire

The following questions are based on your experience as a key leader in regulatory affairs in your organization.

22. **Regulatory Affairs functions are key to a pharmaceutical company as it lays down the basis for all other pharmaceutical functions, and ensures that the company is legally compliant to commence business. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

23. **It is critical for the reputation of the business & the pharmaceutical industry that regulatory affairs be given adequate and competent resources to carry out their functions. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

24. **Regulatory affairs functions are taught in pharmacy schools at an undergraduate level. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

25. **Regulatory affairs functions are taught in pharmacy schools at a post graduate level. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

26. **I suggest that regulatory affairs be taught as a specialization in pharmacy at an undergraduate level, in order to have more competent graduates entering the pharmaceutical industry sector. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

27. **It is better to train regulatory affairs pharmacists fully only once they enter the pharmaceutical industry due to the nature of the work. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

28. **Recent graduates (straight out of university), that I employed as regulatory affairs pharmacists were competent for their role. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

29. **Recent graduates (straight out of varsity), that I employed as regulatory affairs pharmacists were not competent, but were familiar to some degree with regulatory affairs, due to academic learning e.g. intern programme. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

30. **Recent graduates (straight out of varsity), that I employed as regulatory affairs pharmacists were not competent, but were familiar to some degree with regulatory affairs, due to their prior exposure to the pharmaceutical industry ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

31. **It currently takes on average the following duration for new regulatory affairs pharmacists to become fully competent in their role. ***

Please choose the duration below which you think is most realistic

Mark only one oval.

- ☐ 0 to 6 months
- ☐ 6 to 12 months
- ☐ 12 to 24 months
- ☐ 24 to 36 months
- ☐ more than 36 months

32. **I am willing to collaborate with pharmacy schools to develop a curriculum for undergraduate students, should there be a need. ***

Please choose the option below that best describes your response

Mark only one oval.

- ☐ strongly agree
- ☐ agree
- ☐ neutral
- ☐ disagree
- ☐ strongly disagree

Questions Relating to Recent Graduates

With reference to your responses regarding recent graduates in the previous section, please tick one box for each option below to indicate if recent graduates were mostly COMPETENT or mostly INCOMPETENT in the listed regulatory functions, or if these functions were NOT APPLICABLE.

33. **Knowledge of Pharmacy Legislation ***

Please choose one option below that describes competency of recent graduates

Check all that apply.

- ☐ Mostly competent
- ☐ Mostly incompetent
- ☐ Not applicable

34. Dossier Compilation *

Please choose one option below that describes competency of recent graduates

Check all that apply.

- ☐ Mostly competent
- ☐ Mostly incompetent
- ☐ Not applicable

35. Production support *

Please choose one option below that describes competency of recent graduates

Check all that apply.

- ☐ Mostly competent
- ☐ Mostly incompetent
- ☐ Not applicable

36. Supply Chain Support *

Please choose one option below that describes competency of recent graduates

Check all that apply.

- ☐ Mostly competent
- ☐ Mostly incompetent
- ☐ Not applicable

37. Quality Assurance Support *

Please choose one option below that best describes competency of recent graduates

Check all that apply.

- ☐ Mostly competent
- ☐ Mostly incompetent
- ☐ Not applicable

38. Marketing Support *

Please choose one option below that best describes competency of recent graduates

Check all that apply.

- ☐ Mostly competent
- ☐ Mostly incompetent
- ☐ Not applicable

39. Pharmaceutical Knowledge *

Please choose one option below that best describes competency of recent graduates

Check all that apply.

- ☐ Mostly competent
- ☐ Mostly incompetent
- ☐ Not applicable

40. Clinical Knowledge *

Please choose one option below that best describes competency of recent graduates

Check all that apply.

- ☐ Mostly competent
- ☐ Mostly incompetent
- ☐ Not applicable

41. Other

Please add any other regulatory functions not mentioned above and specify if recent graduates were mostly COMPETENT or mostly INCOMPETENT.

42. Please make suggestions (if any) for areas in regulatory affairs practices to be included in a future regulatory affairs module of the B. Pharm undergraduate curriculum:

Please describe your suggestions briefly in the space provided below

43. Should you wish to be informed of the outcome of this study, please provide your email address in the space below.

44. Should you wish to disclose the name of your organisation, please provide this in the space below.

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Appendix 3: Approved Research Protocol

Post Graduate Committee
 Wits Medical School
 7 York Road
 PARKTOWN
 2193
 Johannesburg

28 February 2014

Dear Sir / Madam

RE: M MOONSAMY (STUDENT NUMBER:0208316J) RECOMMENDATIONS FOR RESEARCH PROTOCOL – MSC. MED PHARMACOTHERAPY (REGULATORY AFFAIRS)

Please find herewith the following attachments:

1. Student's letter, and revised protocol in response to review by Protocol committee, dated 20th June 2013.
2. Revised protocol indicating deletion and addition of text by strike through and underlining, respectively. (February 2014)
3. Assessor report, from Protocol committee, dated 20th February 2013
4. Assessor comments received via email – September 2013
5. Title change form & approval
6. Ethics approval
7. Proof of registration - 2014
8. Supervisor's Approval

Below is a detailed response to Protocol review dated 12th September 2013.

- 1. The student has merely repeated each comment as far as I can tell (as there is no evidence of the original comments), rather than responding to each comment, so one has to scroll through both versions of the protocol to see what she has actually changed. There is no indication if she has or has not addressed each comment. She has also not highlighted the changes which would have assisted in this process.**

The changes suggested by the committee were taken into account and they are indicated in the attached revised protocol and have now been highlighted as follows:

- Deleted text is indicated by strike through
- Additional text is indicated by underlining

Individual responses to these suggestions have been addressed in point 2 below.

2. **On closer review, it is apparent that the student has NOT addressed all the comments satisfactorily. For example, the objectives, as written in the revised protocol, are not objectives at all – they are steps that will be followed to achieve the aim, and need to be revised (comment no.6); the issue of electronic reminders remains (comment no. 7) – again, with no explanation from the student, one cannot assess her ‘non’ response; she has misinterpreted the issue of inclusion vs exclusion criteria (comment no. 9); the number of samples has been increased (comment no. 10) but the student has not said that this is due to a recalculation or explained what was wrong with the initial calculation.**

Please see comments below, relating to specific changes referred to above, as made in the review by the protocol committee. The first 3 are in response to the three comments found on the assessors form. Other constructive recommended changes made verbally by the assessors during the assessor meeting, but not recorded on the assessors form, are included below (points 1-4) and have also been reflected in the latest protocol. Additional related changes have been made separately under point 5.

Comments on assessor form:

1. Title – Comment: Need to redefine the title of the research
 - a. Title was changed to be more specific to the study and to correspond with objectives (Title Section, page 1, paragraph 1); this alteration in title has officially been accepted by Faculty Postgraduate Office.
2. Methods – Comment : More detail in Methods
 - a. Removed references to “follow up” on responses to questionnaires, and revised to send out “electronic reminders” only, to avoid participants feeling compelled to participate, as responses are not mandatory. This has been addressed in the Methods Section 4.2, page 8, paragraph 2.
 - b. Removed methods which do not apply to revised objectives. This was done in the Methods Section, page 6, paragraph 1.
 - c. Exclusion criteria is specifically mentioned and not deemed to be the opposite of those mentioned in inclusion criteria. This was corrected in the Methods section 4.2, page 8, paragraph 4.
 - d. In consultation with a Wits statistician, the number of samples were recalculated for statistical significance as initially it was not calculated correctly (Methods 4.2, page 9, paragraph 4)
3. Questionnaires – Comment : Need to do a new job description.

- a. A job description has been included in Appendix 3, pages 20-22, Letter to pharmaceutical companies. This is in a tabulated tick box format, to allow participants to tick off relevant job functions instead of describing them, to enable quantifying responses for data analysis.

Additional editions to the reviewed protocol as per verbal Assessor comments:

1. Introduction – Comments: Remove assessment of legislation as a part of study as this has already been addressed as a possible cause in the protocol.
 - a. References to assessment of legislation were removed from *Introduction and Objectives* (Introduction, page 5, paragraph 3 & Objectives, page 6, paragraph 1)
 - b. The wording of the aim of the study was changed to correspond with the revised title (Introduction, page 5, paragraph 4)
 - c. The comment regarding proposals to improve training of regulatory affairs pharmacists was removed from *Objectives* and inserted in *Introduction* (removed from page 6, paragraph 2 and inserted in page 5, last paragraph)
2. Include *Hypothesis* section
 - a. This was done in Introduction, page 6, paragraph 1
3. Objectives – Comment: “simplify objectives”
 - a. This was addressed on page 6, paragraph 3, where objectives were reduced from four to two.
4. Data Analysis – Comment : Remove reference to consult a statistician in the future, as this must be done prior to finalizing protocol
 - a. A Wits statistician was consulted in February & March 2013 to assist with this. On her advice it was decided that frequencies, means and medians would be the primary means of analysis. This is indicated in the Data Analysis section, page 10, paragraph 4.
 - b. Her advice was to also change the content of survey questionnaires with regards to response indicators in order to allow them to be quantified during analyses i.e. to change A, B, C, D & E to being 1, 2, 3, 4 & 5 (Appendix 2 & 4, pages 18 & 24)
 - c. The statistician also provided guidance on the methods of analysis for each set of data to be collected. This has now been included in detail under Data Analysis section, page 10 and 11.
5. Other Additional Changes
 - a. Methods 4.2. pages 8 -9, the order of the text from the last paragraph on page 8 to the last paragraph on page 9 has been changed to be more flowing. The changes have been indicated by strike through for deletions and underlining for additions.

- b. Ethics – submission date was changed to correspond with later time period when it was actually sent. Approval was received on 07/08/2013 and the clearance certificate number is M130655. These have been included in Ethics page 11, last paragraph.
- c. Timing – this was changed to correspond with new protocol assessment dates (Timing, Table, page 12).
- d. Funding – information has been tabulated (Funding, table, page 13)
- e. Appendix 1 – *Title* changed in letter to correspond with revised title and deadline for collating information updated according to *Timing* (Appendix 1, page 16, paragraph 1 and page 17, paragraph 2)
- f. Appendix 3 – *Title* changed in letter to correspond to revised title and deadline for collating information updated according to *Timing* (Appendix 3. page 20, paragraph 1 and page 22, paragraph 4).

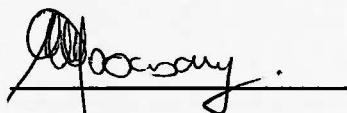
3. The timing is out again due to the long delay (comment 12 and 13) although this is not the fault of Miss Moonsamy.

Noted. The timing has been adjusted in anticipation of protocol being approved by February or March 2014. Ethics approval was granted on 07/08/2013 (clearance certificate number is M130655).

I trust you will find this in order in the revised protocol.

Thanking you

Yours faithfully



M.R. Moonsamy (Miss)

Student No. 0208316J

Mobile No: +27 82 3211 789

e-mail: marlenem1810@gmail.com

Post Graduate Committee

Wits Medical School

7 York Road

PARKTOWN

2193

Johannesburg

20 June 2013

Dear Sir / Madam

RE: Recommendations by Assessors of Post Grad Committee for Research Protocol – MSc. Med Pharmacotherapy (Regulatory Affairs).

Please see attached, assessor report, dated 20th February 2013.

In addition, the following verbal recommendations were made by the assessors and these were taken into account during revision of the updated protocol.

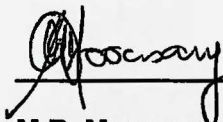
1. Title - change title to be more specific and to correspond with objectives
2. Introduction - remove references to assessment of legislation from *Introduction and Objectives* as this will not be in scope.
3. Introduction - change the wording of the aim of the study to correspond with the revised title.
4. Remove the comment regarding proposals to improve training of regulatory affairs pharmacists from *Objectives* and insert in *Introduction*
5. Include *Hypothesis*
6. Objectives - simplify objectives
7. Methods - remove references to "follow up" on responses to questionnaires, and revise to send out "electronic reminders", to avoid participants feeling compelled to participate, as responses are not mandatory.
8. Methods - remove methods which do not apply to revised objectives.
9. Methods - exclusion criteria must be specifically mentioned and not deemed to be the opposite of those mentioned in inclusion criteria.
10. Methods - the number of samples must be recalculated for statistical significance is it does not appear to be correct.
11. Data Analysis – remove reference to consult a statistician in the future, as this must be done prior to finalizing protocol.

12. Ethics – change submission date to correspond with later time period when protocol will be updated.
13. Timing – change timing to correspond with new protocol assessment dates.
14. Funding – tabulate information
15. Appendix 1 – *Title* changed in letter to correspond to revised title and deadline for collating information updated according to *Timing*.
16. Appendix 3 – *Title* changed in letter to correspond to revised title and deadline for collating information updated according to *Timing*.
17. Appendix 3 – include tick box for regulatory job functions to eliminate the need for descriptions and to be able to quantify responses.

I trust you will find this in order in the revised protocol.

Thanking you

Yours faithfully

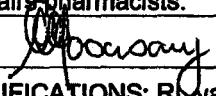
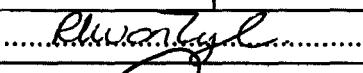
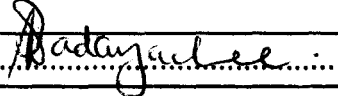


M.R. Moonsamy (Miss)

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CANDIDATE'S SURNAME: [Please print]	MOONSAMY	FIRST NAME/S:	MARLENE ROSE	STUDENT NUMBER:	0208316J
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DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: MSc. Med Pharmacotherapy.					
PART-TIME/FULL-TIME: Part time				Sex :	F ☐ M ☒
DISSERTATION/RESEARCH REPORT: RESEARCH REPORT			23 % contribution towards degree		
FIRST REGISTERED FOR THIS DEGREE:		TERM : ONE		YEAR: 2010	
DEPARTMENT: PHARMACY AND PHARMACOLOGY					
TITLE OF PROPOSED RESEARCH: Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists.					
CANDIDATE'S SIGNATURE: 				DATE: 03 JUNE 2013	
SUPERVISOR'S NAME/QUALIFICATIONS: RL van Zyl (BSc, PhD)				% Supervision 50	
SUPERVISOR'S DEPARTMENT: Pharmacy and Pharmacology					
SUPERVISOR'S ADDRESS / TEL / E-MAIL: 011-717-2271 / Robyn.vanZyl@wits.ac.za					
SUPERVISOR'S NAME/QUALIFICATIONS: N. Padayachee (BPharm, MPharm)				% Supervision 50	
SUPERVISOR'S DEPARTMENT Pharmacy and Pharmacology					
SUPERVISOR'S ADDRESS / TEL / E-MAIL: 011-717-2269 / Neelaveni Padayachee@wits.ac.za					
SYNOPSIS OF RESEARCH: [Use reverse side of this page if more space is required]					
Please see reverse.					
ETHICS PENDING:		to apply in June 2013		IF Y SUPPLY ETHICS	
ETHICS APPROVED: (circle appropriate symbol)		N		CLEARANCE No:	
SIGNATURE OF SUPERVISOR/S:	 		 		
PROTOCOL ACCEPTED BY HEAD OF DEPARTMENT	  SIGNATURE		11/7/13..... DATE		
SIGNATURE PG OFFICE STAFF	REGISTERED YES..... NO.....		STAMP		

SYNOPSIS OF RESEARCH CONTINUED

National governments are required to protect the health of the public. In pharmacy, this is established by the medicines regulatory authorities which enforce regulatory practices to be executed by pharmaceutical companies. In South Africa, the statutory body that governs the regulation of medicines is the Medicines Control Council (MCC). The mandate of MCC includes maintaining the medicine register to ensure that the safety, quality and efficacy of registered medicines. MCC stipulates the requirements for registration of medicines, via guidelines which are based on the Medicines and Related Substances Act 101 of 1965.

Regulatory affairs pharmacists provide more than scientific and technical support to their stakeholders, therefore their skill sets must be broader. Global expansion of regulatory affairs has resulted in significant skills shortage. Studies have shown that a lack of education in regulatory affairs is partially responsible for the shortage of regulatory affairs professionals. Lack of communication between academia and industry further contributes to this skills shortage.

In South Africa, courses offered by pharmacy schools are registered and approved by the South African Pharmacy Council (SAPC) in keeping with The Pharmacy Act (Act 53 of 1974). Regulatory practices however, are determined by the guidelines published by MCC in keeping with the Medicines and Related Substances Control Act.

Published data shows that there are inconsistencies between the Medicines Act and The Pharmacy Act, which may contribute to the gaps between undergraduate education and regulatory practice in industry. Key areas to examine in assessing this would be job descriptions compiled by pharmaceutical companies and the undergraduate curriculum of the bachelor of pharmacy degree offered by pharmacy schools in South Africa.

The aim of this study is to assess if the correlation between tertiary education and pharmaceutical industry to determine if graduating pharmacists, entering industrial pharmacy are equipped for their role in regulatory affairs.

A qualitative and quantitative comparative analysis will be conducted to demonstrate gaps, if any, in the requirements for regulatory practices in industry. Survey studies will be conducted in pharmacy schools and in the pharmaceutical industry to understand the gaps between what is taught and what is required. Results of the study will be shared with participants wishing to understand the outcome and willing to collaborate to improve the education of regulatory affair pharmacists.

1.TITLE

Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists.

2. INTRODUCTION

It is the responsibility of national governments all over the world to protect the health of the public. In industrial pharmacy, this is done by establishing robust medicines regulatory authorities, which are accountable to the government and the public and which practice transparent decision-making processes (WHO, 2013).

2.1 Regulatory practices

Regulatory practices are established by regulatory authorities and encompass a set of activities, to be executed by pharmaceutical companies to ensure the protection of the public by controlling the safety, quality and efficacy of medicines, during their development, manufacture, testing and marketing (Dheyongera, 2011: 38; MCC Guideline 2.01, 2013: 1).

Some regulatory practices to be maintained are the following: Ensure appropriate manufacture, storage, distribution and dispensing of medicines; health professionals and patients must be provided with the required information to help them to use medicines rationally; promotion and advertising of medicines by the industry must be fair, balanced and aimed at rational drug use; access to medicines must not be hampered by unjust regulatory practices and illegal manufacture and trade of medicines must be detected and appropriately sanctioned to prevent the public from obtaining access to them (WHO, 2013).

2.2 Regulatory bodies

In South Africa, the statutory body that currently governs the regulation of medicines is the Medicines Control Council (MCC) which is in the Department of Health (DoH), which was established in terms of the Medicines and Related Substances Act, 1965 (Act No.101 of 1965). The main purpose of the MCC is aligned with that of the World Health Organisation (WHO), which is to protect the public by ensuring that medicines sold in South Africa are safe, efficacious and of acceptable quality (WHO,2013; DoH, 2013; MCC, 2013). This purpose is achieved by prescribing standards to govern the manufacture, distribution, sale and marketing of medicines through published guidelines. The MCC also determines the scheduling status of medicines and medicinal substances to control their prescribing and dispensing (MCC, 2013).

Part of the mandate of the MCC is to maintain the medicine register, register new medicines, amend entries made in the register, transfer registration certificates, cancel registration of discontinued medicines, approve labelling and advertising of medicines and authorize the sale of unregistered medicines under certain conditions (DoH, 2013). This is to ensure that the safety, quality and efficacy of registered medicines are maintained throughout their life-cycle. Changes which occur to these medicines after registration, must also comply with quality, safety and efficacy requirements as stipulated by the MCC (MCC Guideline 2.08, 2013:1).

Some technical changes that may take place after registration may be related to manufacturing, packaging and testing sites, manufacturing and testing methods and pharmaceutical ingredients and their sources. Clinical changes would affect package inserts and patient information leaflets. Package inserts are leaflets accompanying pharmaceutical products, which contain clinical information about the product. Clinical information includes indications, contraindications, dosing instructions, side effects and warnings. Patient information leaflets are an adaptation of the package insert into consumer language for patients. Changes to these documents would normally relate to safety of the medicine (MCC Guideline 2.01, 2013:23-26; MCC Guideline 2.16, 2013:1; MCC Guideline 2.14, 2013:4).

The MCC stipulates the format and data requirements in compiling applications for registration of medicines and applications to make changes to registered medicines, via published guidelines. These guidelines are based on the Medicines and Related Substances Act 101 of 1965 and its regulations (MCC Guideline 2.01, 2013:1).

The MCC aligns itself with established regulatory health authorities around the world, such as Food & Drug Administration (USA), European Union (EMA and National Regulatory Authorities), and MWH (Japan). It also aligns to Swissmedic (Switzerland), Health Canada (Canada) and Therapeutic Goods Association (Australia), to ensure that regulatory practices in South Africa are harmonized with internationally accepted standards (MCC Guideline 2.01, 2013:1&14).

The MCC is currently undergoing a transition to become a new public entity known as the South African Health Products Regulatory Agency (SAHPRA), which will manage registration, regulation and control of health products such as medicines and medical devices. Due to legislative changes that first need to be passed by Parliament, this transition may occur in 2013 (Schaay *et al.*, 2011:16).

2.3 Scope of Practice in Industry

In regulatory affairs practices in industry, pharmacists provide more than scientific and technical support to their internal and external stakeholders. Their scope of practice includes being familiar with legislation governing medicine registrations, compiling medicine registration applications for human, veterinary, biological or homeopathic medicine, managing the registration process, controlling pharmaceutical advertising, updating and maintaining regulatory licences and supporting the sales and marketing functions in a company (Health Science Academy, 2013). In addition, they are expected to be experts in the technology of the products they manage (Robinson 2006:18). It therefore stands to reason that their skill sets must be broader than scientific and technical qualifications.

Most companies operate on a multinational basis making exportation of medicines a key component of their business. This requires that regulatory affairs pharmacists continually monitor, analyse and interpret the practices and requirements of health authorities in their export markets in order to inform their internal stakeholders of regulatory trends and matters (Dheyongera, 2011:38).

The Marketing Code was issued by pharmaceutical trade associations in terms of the Medicines and Related Substances Act No 101 of 1965 to establish responsible, ethical and professional marketing of health products to healthcare professionals and the public. This Code takes into account advertising and labelling restrictions based on the scheduling status of medicines and the audience to which these medicines are advertised. For example, Schedule 0 medicines may be advertised directly to consumers, but Schedule 5 medicines may only be advertised to health care professionals with more restrictions to the content of the advertisement (SA Marketing Code, 2010: 5-7). A thorough understanding of the marketing code is required, since regulatory affairs is involved in developing marketing concepts and in approving advertising and packaging material (Dheyongera, 2011).

Globally, the regulation of medical products has been expanding since the early 20th century and has now 'mushroomed', resulting in significant strains on experienced regulatory affairs professionals. The shortage of regulatory affairs professionals is seen as 'massive' with the expectation that regulatory demands will continue to increase. (Robinson, 2006:18). In each country, the capacity to provide adequate pharmaceutical services depends on two workforce needs, that is an appropriately trained pharmacy workforce and a committed academic workforce to train new pharmacists (Anderson *et al.*, 2009, 7:45).

2.4 Regulatory education

Various studies around the world have shown that the lack of education in regulatory affairs is partially responsible for the shortage of regulatory affairs professionals. In the UK, pharmacy students do not seem to have sufficient information about the pharmaceutical industry, as most pharmacy schools give little attention to industrial pharmacy compared with other careers. Pharmacists in industry however, perceive regulatory affairs to be a prominent career opportunity. It is clear that undergraduates need to be made aware of the opportunities to develop their careers in regulatory affairs (Kirby-Smith, 2012).

In the US and Europe, continuing education by regulatory affairs organizations, has been useful in developing and maintaining the regulatory knowledge of their members (who are already involved in regulatory affairs), but a possible further solution may be to educate new regulatory affairs professionals in academic institutions. While practical experience is preferred over academic qualifications, employers and academic institutions are perceived to both bear the responsibility of filling the gaps by partnering with each other to meet the needs of students and prospective employers (Robinson, 2006: 20; 23).

In Australia, the Pharmaceutical Education Council (PEC) which was set up to assess the skills gap between government and tertiary institutions, maintains that “a lack of communication between industry and academia means that industry do not know what is available to them and academia do not know what industry wants”. They therefore encourage a two-way partnership between industry and academia. Of the technical skills found to be lacking in new graduates, training and experience in regulatory affairs featured at the top of the list (PEC, 2007:88,91,96,103).

In India, the pharmaceutical industry is a rapidly growing sector, making it part of the global competition. The pharmaceutical industry is one of the most highly regulated industries; coupled with the current global competition, the progressive need for regulatory affairs professionals cannot be over emphasized. It is of urgency that the current requirements of pharmaceutical industries be incorporated into the standard curriculum of pharmacy schools. To address this issue, two universities in India have taken initiatives to offer Pharmaceutical Regulatory Affairs as a subject in a post-graduate course (Songara 2011:122-123).

In South Africa, no published articles were found to describe possible inconsistencies in the current regulatory framework, such as a comparison of legislative requirements, pharmacy education and industry practices.

With regard to pharmacy education however, courses offered by pharmacy schools are registered and approved by the South African Pharmacy Council (SAPC) for professional reasons. The SAPC is responsible for establishing and overseeing standards for education and license registrations (Summers, 2001:150-154). It conforms to The Pharmacy Act (Act 53 of 1974), which was amended in 1997 for provisions relating to pharmacy education and training requirements for registration (Pearmain, 2012:27). The amendment included the addition of seven unit standards, which were prescribed for the education and training of pharmacists to form their scope of practice (Government Gazette, 20 November 2000, No. 21754).

Regulatory practices in industry however, are determined by the guidelines published by the MCC in keeping with the Medicines and Related Substances Control Act (Act 101 of 1965), as mentioned earlier, and not The Pharmacy Act. It was also noted in a local publication that for some inconsistencies in health legislation, possible amendments may be required to The Pharmacy Act to bring it in line with The Medicines and Related Substances Act (Pearmain, 2012: 26).

Key areas to assess the correlation between education and regulatory practices in industry, would be job descriptions compiled by pharmaceutical companies and the undergraduate curriculum of the Bachelor of Pharmacy degree offered by Pharmacy schools in South Africa.

The aim of this study in assessing this correlation is to determine if graduating pharmacists, entering industrial pharmacy are equipped for their role in regulatory affairs.

At the end of the study, proposals to improve the training and performance of regulatory affairs pharmacists in the affected sectors will be presented if needed.

HYPOTHESIS

Pharmacist tertiary education and pharmaceutical industry requirements are not sufficiently correlated to allow pharmacists entering the pharmaceutical industry to be equipped for their role in regulatory affairs.

3.STUDY OBJECTIVES

Compare regulatory education and industrial practices as follows to assess deficiencies in the required competencies of a regulatory affairs pharmacist.

- i. The appropriate section in Pharmacy curriculum from all eight Pharmacy schools in South Africa to assess the level to which regulatory affairs is taught
- ii. Job descriptions of regulatory affairs pharmacists to assess the functional competencies required.

4. METHODS

In order to compare regulatory education and industrial requirements of a regulatory affairs pharmacist, an investigative survey study will be conducted as follows:

4.1. Acquisition of academic curriculum

In order to review the extent to which regulatory affairs is taught, Heads of Department of Pharmacy at the Universities of Witwatersrand, Western Cape, Limpopo, Kwazulu-Natal, North West, Rhodes and Nelson Mandela Metropolitan Universities (SAPC 2012) will be contacted and permission acquired to obtain copies of the undergraduate curriculum for Pharmacy Practice from 1st year to 4th year. This request will include details of duration and content of pharmacy practice courses relating specifically to regulatory affairs (See Appendix 1). The undergraduate curriculum from the eight pharmacy schools will be tabulated to demonstrate common and different modules / themes so that regulatory functions can be grouped together and highlighted. Pharmacy schools which provide regulatory affairs education at a post graduate level will also be requested to provide copies of their curriculum for comparative review,

In order to assess their awareness of the functions of regulatory affairs pharmacists and the level to which regulatory affairs is taught, questionnaires will be sent to academic staff responsible for teaching pharmacy practice (See Appendix 2). To ensure maximum receipt of responses, telephonic or electronic reminders will be sent where necessary.

4.2. Assessment and comparison of current regulations with job descriptions, prescribed scope of practice and undergraduate curriculum.

Pharmaceutical companies (local and multi-national) will be approached to provide job descriptions for staff in their regulatory affairs department. This will be to assess company requirements to fulfill the functions of a regulatory role. Letters will be addressed to The Responsible Pharmacist / Human Resources Manager, stating the purpose of study and requesting copies of job descriptions for regulatory affairs pharmacists (Appendix 3). To ensure maximum receipt of responses, telephonic or electronic reminders will be sent where necessary and appropriate.

In order to cover various types of pharmaceutical manufacturers and medicinal products, pharmaceutical companies will be selected according to the types of pharmaceutical products that they manufacture viz. ethical medicines, generic medicines and consumer (OTC) health products.

Inclusion criteria will be pharmaceutical companies, which are registered with SAPC, which have a central in-house regulatory department, and which manufacture or import ethical, generic or consumer (OTC) medicines. Exclusion criteria will be pharmaceutical companies, which are not registered with SAPC, which outsource their regulatory affairs functions and which manufacture or import biological medicines, medical devices, veterinary medicines and complementary medicines.

There are currently 267 manufacturing pharmacies, which are registered with SAPC (SAPC, 2012). The following formula will be used to calculate the number of pharmacies required to participate in this study (sample size) to obtain a 5 % statistical significance (or 95 % confidence level) (Survey system website, 2012).

$$n^* = \frac{z^2 p(1-p)}{d^2}$$

Where $Z = 1.96$ (e.g. 1.96 for 95% confidence level)

$p = 0.5$ (proportion of pharmaceutical companies that have the outcome of interest)

$d = 0.04$ (4% precision allowed)

Adjusting for the population size, the minimum sample size will be

$$Ss = \frac{n^*}{1 + \frac{n^*}{N}} \text{ where } n^* \text{ is the sample size calculated and } N \text{ is the number of eligible}$$

pharmaceutical companies.

The inclusion and exclusion criteria will further determine the actual sample size to be used and should all 267 pharmaceutical companies currently registered with SAPC, be eligible to participate, 185 responses per question will be required to obtain statistical significance. The actual sample size will be finalised once the inclusion and exclusion criteria have been considered for each company.

Details of job descriptions will be tabulated to compare them with each other in terms of common functions and specialized functions, according to the type of pharmaceutical products manufactured, to identify key areas of commonality. These job descriptions will then be compared with the undergraduate curriculum and prescribed scope of practice to determine the extent to which regulatory functions are covered in the curriculum .

Questionnaires will be sent to heads of regulatory affairs at the same pharmaceutical companies selected to request job descriptions, in order to determine their view on the level of competence found in recent graduates employed as regulatory affairs pharmacists (Appendix 4). As with the request for job descriptions, telephonic or electronic follow up and personal interviews will be conducted where necessary and appropriate.

Once results have been collated and analysed, the sectors showing the greatest need for improvement in exposure to regulatory affairs, will be assessed individually for specific deficiencies and solutions proposed. Proposals for collaboration between pharmacy schools and industry will be offered, and willingness to participate will be assessed in advance in the study questionnaires. Details of the pharmacy schools and pharmaceutical companies which opt to collaborate will be provided to the South African Pharmacy Council to allow co-ordination of this where possible.

5. DATA ANALYSIS

For easy comparison, results from the various surveys will be tabulated for responses to each question according to the options provided and compared to the published regulatory requirements. For qualitative analysis, comparison of responses will be collated, and for quantitative analysis, statistics will be done to determine if there is significance in the responses. A statistician was consulted for advice on the appropriate tests to be used to analyse noticeable trends for key questions. It was decided that frequencies, means and medians will be the primary means of analysis.

6. ETHICS

Submission to the Ethics committee will be done in June 2013.

7. TIMING

	Oct 2012	Nov 2012	Dec 2012	Jan 2013	Feb 2013	Mar 2013	Apr 2013	May 2013	Jun 2013	Jul 2013	Aug 2013	Sep 2013	Oct 2013
Literature Review													
Prepare Protocol													
Protocol Assessment													
Ethics Application													
Data Collection													
Data Analysis													
Writing up – Thesis													
Writing up – Paper													

8. FUNDING

Anticipated costs for the following will be covered by a grant (to be applied for from Faculty) or self-funded:

No.	Expense	Estimated Cost
1.	Telephone calls to source contact information for pharmacy schools and pharmaceutical companies.	R 500.00
2.	Postal and / or electronic deliveries of letters and questionnaires to pharmacy schools and pharmaceutical companies.	R 1 000.00
3.	Printing costs	R 200.00
4.	Travel costs for personal interviews and completion of surveys (R 1 000.00 (R3.17 / km))	R 1 000.00
5.	TOTAL	R 2 700.00

9. PROBLEMS

- a. Identifying a key contact person in each organization / institution to facilitate communication may cause delays in initiating the study.
- b. Confidentiality code by various sectors / organisations could inhibit the level of transparency of information provided.
- c. Perception of study may be seen as demeaning to some sectors / organisations, resulting in reluctance to provide honest responses.
- d. Response rate and numbers may slow down processing of results and progress of study

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Appendix 1 – Example letter to Pharmacy schools

The Head of Pharmacy Department
 Faculty of Health Sciences
 Medical School - Wits University
 7 York Road
 Parktown
 2193

Dear Sir / Madam

Re: Participation in Study - B.Pharm Undergraduate Curriculum - Regulatory Affairs

I am a postgraduate student at the University of the Witwatersrand currently studying towards an MSc.Med degree in Pharmacotherapy. As part of my studies, I am required to complete a research project. My research topic is "Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists"

This topic entails examining the current undergraduate curriculum in all pharmacy schools in South Africa in order to determine the extent to which Regulatory affairs is taught.

I would be grateful for your contribution to this study by providing details of content and duration of subjects covered in the Pharmacy Practice (or similar) module of the B.Pharm degree from 1st year to 4th year. Should regulatory affairs be covered in any other module or course (including post graduate courses), kindly indicate this and provide the subjects for that particular module or course.

Please also see attached a short questionnaire to be completed in order to further contribute to the outcome of this study.

Please note that all information provided will be kept in strict confidence for use by myself and my supervisors for the sole purpose of this study. No information will be disclosed to any other persons or entities.

At the end of the study we will forward you with results of the outcome and any recommendations that could be made to complement your current curriculum.

Please could you kindly return responses for curriculum content as well as completed questionnaire to me as soon as convenient for you. My deadline for collating this information is the 31st July 2013. My e-mail address is marlenem1810@gmail.com.

I look forward to your kind co-operation in this study.

Yours faithfully

Marlene Moonsamy (082-321-1789)

Mrs N. Padayachee (084-230-2364)

Assoc. Prof. R. van Zyl (083-312-0228)

Appendix 2 – Example Questionnaire 1 – Pharmacy Schools.

Date: _____

Designation of Person completing questionnaire: _____

Name of Pharmacy School: _____

Thank you for choosing to participate in this study. The following questions are based on your role in co-ordinating the curriculum for pharmacy students.

SECTION A

The following five options are represented as 1, 2, 3, 4 or 5.

Please choose your best option for each question below by indicating 1, 2, 3, 4 or 5 in the response column on the right.

1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree

	QUESTION	RESPONSE
1.	I am familiar with the concept of regulatory affairs in pharmaceutical industry	
2.	I am familiar with the requirements of regulatory affairs in industry	
3.	I am familiar with the various acts governing regulatory practice in South Africa.	
4.	I am familiar with the different and changing formats of the registration dossier viz. MBR1, MRF, CTD, eCTD.	
5.	I am familiar with the content of the registration dossier for the various formats - MBR1, MRF, CTD, eCTD.	
6.	I understand the role and functions of the MCC (Medicines Control Council)	
7.	I am familiar with the guidelines published by the MCC	
8.	I am familiar with the various trade associations, which exist to support the pharmaceutical industry in SA, including SAPRAA (South African Pharmaceutical Regulatory Affairs Association).	
9.	I am familiar with the SA Marketing Code of Practice, which regulates the advertising of medicines in South Africa.	

10.	I am aware of the need for pharmacy students in South Africa to be well equipped in regulatory affairs functions by the time they graduate.	
11.	The undergraduate B.Pharm curriculum at this pharmacy school consists of a regulatory affairs module, which covers the main requirements of regulatory functions.	
12.	This school provides regulatory affairs education at a post graduate level.	
13.	I am willing to collaborate with the pharmaceutical industry and trade associations to develop a curriculum for regulatory affairs, should there be a need.	

SECTION B

Please make suggestions (if any) for areas in regulatory to be included in a future regulatory affairs module of the B. Pharm undergraduate curriculum:

Appendix 3 – Example Letter to Pharmaceutical companies

The Human Resource Manager / Responsible Pharmacist

“Company name”

“Address”

“Address”

“Address”

Dear Sir /Madam

RE: Participation in Study - Regulatory Affairs Pharmacist - Job Description

I am a postgraduate student at the university of the Witwatersrand, currently studying towards an MSc.Med degree in Pharmacotherapy. As part of my studies, I am required to complete a research project. My research topic is "Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists"

This topic entails examining job descriptions of regulatory pharmacists in various pharmaceutical companies in South Africa, in order to determine the level of expertise required to perform Regulatory affairs functions.

I would be grateful for your contribution to this study by ticking the following boxes to indicate key regulatory functions which are practiced and comprised in the job description of regulatory affairs pharmacists in your organization.

No.	Job Function of Regulatory Affairs Pharmacist	Yes (✓)	No (✓)
1.	Preparation of medicine registration dossiers for submission to MCC.		
2.	Preparation of medicine registration dossiers for submission to health authorities out of South Africa (export markets).		
3.	Preparation of pharmaceutical amendments of dossiers to submit to MCC (to ensure update of pharmaceutical information in dossier and ensure Quality compliance)		
4.	Preparation of pharmaceutical amendments of dossiers to submit to health authorities out of South Africa (export markets)		

5.	Preparation of clinical amendments / package insert updates to submit to MCC (to ensure update of clinical information in dossier and to ensure Safety & Efficacy compliance)		
6.	Preparation of clinical amendments / package insert updates to submit to health authorities out of South Africa (export markets)		
7.	Approval of Promotional Material for South Africa (Marketing Support)		
8.	Approval of Promotional Material for export markets (Marketing Support)		
9.	Submission and approval of labelling and printed packaging updates.		
10.	Re-registration and licence renewal of products for export markets		
11.	PSUR submissions and Pharmacovigilance support		
12.	Regulatory Intelligence – provide regulatory and/or source legal advice when required.		
13.	Competitor Challenges (co-ordinate the legal process)		
14.	Engage in and support new product launch activities with local, regional and global business.		

Please add any additional regulatory functions not listed above:

Please also see attached a short questionnaire to be completed in order to further contribute to the outcome of this study.

Please note that all information provided will be kept in strict confidence for use by my supervisors and myself for the sole purpose of this study. No information will be disclosed to any other persons or entities.

At the end of the study, upon your request we will forward you the results of the outcome and any recommendations that could be made to complement current regulatory affairs practices in industry.

Please could you kindly return responses for job descriptions as well as completed questionnaire to me as soon as convenient for you. My deadline for collating this information is the 31st July 2013.

My e-mail address is at marlenem1810@gmail.com.

I look forward to your kind co-operation in this study.

Yours faithfully

Marlene Moonsamy (082-321-1789)

Mrs. N. Padayachee (084-230-2364)

Assoc. Prof. R. van Zyl (083-312-0228)

Appendix 4 – Example Questionnaire 2 – Pharmaceutical Companies

Date: _____

Designation of Person completing questionnaire: _____

Name of Pharmaceutical Company : _____

Please answer the following questions about your company by ticking the appropriate box(es):

- Company registered with SAPC as a manufacturing pharmacy?
YES ☐ NO ☐
- In-house Regulatory Affairs Department present?
YES ☐ NO ☐
- Products manufactured:
ETHICAL MEDICINES ☐ GENERIC MEDICINES ☐
OTC / CONSUMER MEDICINES ☐ OTHER ☐
Please provide details for OTHER (if applicable): _____

Thank you for choosing to participate in this study. The following questions are based on your experience as a key leader in regulatory affairs in your organization.

SECTION A

The following five options are represented as 1, 2, 3, 4 or 5.

Please choose your best option for each question below by indicating 1, 2, 3, 4 or 5 in the right margin.

1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree

	QUESTION	RESPONSE
1.	Regulatory Affairs functions are key to a pharmaceutical company as it lays down the basis for all other pharmaceutical functions, and ensures that the company is legally compliant to commence business.	
2.	It is critical for the reputation of the business & the pharmaceutical industry that regulatory affairs be given adequate and competent resources to carry out their functions.	
3.	Regulatory affairs functions are taught in pharmacy schools at an undergraduate level.	
4.	Regulatory affairs functions are taught in pharmacy schools at a post graduate level.	
5.	I suggest that regulatory affairs be taught as a specialization in pharmacy at an undergraduate level, in order to have more competent graduates entering the pharmaceutical industry sector.	
6.	It is better to train regulatory affairs pharmacists fully only once they enter the pharmaceutical industry due to the nature of the work.	
7.	Recent graduates (straight out of university), that I employed as regulatory affairs pharmacists were competent for their role.	

8.	Recent graduates (straight out of varsity), that I employed as regulatory affairs pharmacists were not competent, but were familiar to some degree with regulatory affairs, due to academic learning e.g. intern programme.	
9.	Recent graduates (straight out of varsity), that I employed as regulatory affairs pharmacists were not competent, but were familiar to some degree with regulatory affairs, due to their prior exposure to the pharmaceutical industry	
10.1	It currently takes on average 0 to 6 months for new regulatory affairs pharmacists to become fully competent in their role.	
10.2	It currently takes on average 6 to 12 months for new regulatory affairs pharmacists to become fully competent in their role.	
10.3	It currently takes on average 12 to 24 months for new regulatory affairs pharmacists to become fully competent in their role.	
10.4	It currently takes on average 24 to 36 months for new regulatory affairs pharmacists to become fully competent in their role.	
10.5	It currently takes more than 36 months for new regulatory affairs pharmacists to become fully competent in their role.	
11.	I am willing to collaborate with pharmacy schools to develop a curriculum for undergraduate students, should there be a need.	

SECTION B

Please complete the following sections for further details to above responses

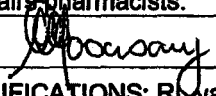
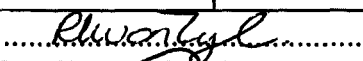
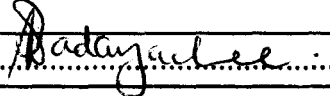
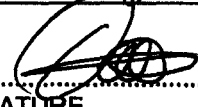
1. With reference to responses in Question 7, 8 & 9 of the survey above, please tick the appropriate boxes below:

Recent graduates were mostly competent in:		Recent graduates were mostly incompetent in:	
Knowledge of legislation	☐	Knowledge of legislation	☐
Dossier Compilation	☐	Dossier Compilation	☐
Production support	☐	Production support	☐
Supply Chain support	☐	Supply Chain support	☐
Quality Assurance support	☐	Quality Assurance support	☐
Marketing support	☐	Marketing support	☐
Pharmaceutical knowledge	☐	Pharmaceutical knowledge	☐
Clinical knowledge	☐	Clinical knowledge	☐
Other (please elaborate below):	☐	Other (please elaborate below):	☐

Other (competent): _____

Other (incompetent): _____

2. Please make suggestions (if any) for areas in regulatory to be included in a future regulatory affairs module of the B. Pharm undergraduate curriculum:

CANDIDATE'S SURNAME: [Please print]	MOONSAMY	FIRST NAME/S:	MARLENE ROSE	STUDENT NUMBER:	0208316J
CURRENT QUALIFICATIONS: B.PHARM					
TEL: 021 710 4609	CELL: 082 3211 789	E-MAIL: marlenem1810@gmail.com		FAX: 021 710 4613	
DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: MSc. Med Pharmacotherapy.					
PART-TIME/FULL-TIME: Part time				Sex :	F ☐ M ☒
DISSERTATION/RESEARCH REPORT: RESEARCH REPORT			23 % contribution towards degree		
FIRST REGISTERED FOR THIS DEGREE:		TERM : ONE		YEAR: 2010	
DEPARTMENT: PHARMACY AND PHARMACOLOGY					
TITLE OF PROPOSED RESEARCH: Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists.					
CANDIDATE'S SIGNATURE: 				DATE: 03 JUNE 2013	
SUPERVISOR'S NAME/QUALIFICATIONS: RL van Zyl (BSc, PhD)				% Supervision 50	
SUPERVISOR'S DEPARTMENT: Pharmacy and Pharmacology					
SUPERVISOR'S ADDRESS / TEL / E-MAIL: 011-717-2271 / Robyn.vanZyl@wits.ac.za					
SUPERVISOR'S NAME/QUALIFICATIONS: N. Padayachee (BPharm, MPharm)				% Supervision 50	
SUPERVISOR'S DEPARTMENT Pharmacy and Pharmacology					
SUPERVISOR'S ADDRESS / TEL / E-MAIL: 011-717-2269 / Neelaveni Padayachee@wits.ac.za					
SYNOPSIS OF RESEARCH: [Use reverse side of this page if more space is required]					
Please see reverse.					
ETHICS PENDING:		to apply in June 2013		IF Y SUPPLY ETHICS	
ETHICS APPROVED: (circle appropriate symbol)		N		CLEARANCE No:	
SIGNATURE OF SUPERVISOR/S:	 		 		
PROTOCOL ACCEPTED BY HEAD OF DEPARTMENT	  SIGNATURE		11/7/13..... DATE		
SIGNATURE PG OFFICE STAFF	REGISTERED YES..... NO.....		STAMP		

SYNOPSIS OF RESEARCH CONTINUED

National governments are required to protect the health of the public. In pharmacy, this is established by the medicines regulatory authorities which enforce regulatory practices to be executed by pharmaceutical companies. In South Africa, the statutory body that governs the regulation of medicines is the Medicines Control Council (MCC). The mandate of MCC includes maintaining the medicine register to ensure that the safety, quality and efficacy of registered medicines. MCC stipulates the requirements for registration of medicines, via guidelines which are based on the Medicines and Related Substances Act 101 of 1965.

Regulatory affairs pharmacists provide more than scientific and technical support to their stakeholders, therefore their skill sets must be broader. Global expansion of regulatory affairs has resulted in significant skills shortage. Studies have shown that a lack of education in regulatory affairs is partially responsible for the shortage of regulatory affairs professionals. Lack of communication between academia and industry further contributes to this skills shortage.

In South Africa, courses offered by pharmacy schools are registered and approved by the South African Pharmacy Council (SAPC) in keeping with The Pharmacy Act (Act 53 of 1974). Regulatory practices however, are determined by the guidelines published by MCC in keeping with the Medicines and Related Substances Control Act.

Published data shows that there are inconsistencies between the Medicines Act and The Pharmacy Act, which may contribute to the gaps between undergraduate education and regulatory practice in industry. Key areas to examine in assessing this would be job descriptions compiled by pharmaceutical companies and the undergraduate curriculum of the bachelor of pharmacy degree offered by pharmacy schools in South Africa.

The aim of this study is to assess if the correlation between tertiary education and pharmaceutical industry to determine if graduating pharmacists, entering industrial pharmacy are equipped for their role in regulatory affairs.

A qualitative and quantitative comparative analysis will be conducted to demonstrate gaps, if any, in the requirements for regulatory practices in industry. Survey studies will be conducted in pharmacy schools and in the pharmaceutical industry to understand the gaps between what is taught and what is required. Results of the study will be shared with participants wishing to understand the outcome and willing to collaborate to improve the education of regulatory affair pharmacists.

1. TITLE

Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists. ~~Assessment of legislation, education and industry practices to identify inconsistencies in meeting regulatory affairs requirements.~~

2. INTRODUCTION

It is the responsibility of national governments all over the world to protect the health of the public. In industrial pharmacy, this is done by establishing robust medicines regulatory authorities, which are accountable to the government and the public and which practice transparent decision-making processes (WHO, 2013).

2.1 Regulatory practices

Regulatory practices are established by regulatory authorities and encompass a set of activities, to be executed by pharmaceutical companies to ensure the protection of the public by controlling the safety, quality and efficacy of medicines, during their development, manufacture, testing and marketing (Dheyongera, 2011: 38; MCC Guideline 2.01, 2013: 1).

Some regulatory practices to be maintained are the following: Ensure appropriate manufacture, storage, distribution and dispensing of medicines; health professionals and patients must be provided with the required information to help them to use medicines rationally; promotion and advertising of medicines by the industry must be fair, balanced and aimed at rational drug use; access to medicines must not be hampered by unjust regulatory practices and illegal manufacture and trade of medicines must be detected and appropriately sanctioned to prevent the public from obtaining access to them (WHO, 2013).

2.2 Regulatory bodies

In South Africa, the statutory body that currently governs the regulation of medicines is the Medicines Control Council (MCC) which is in the Department of Health (DoH), which was established in terms of the Medicines and Related Substances Act, 1965 (Act No.101 of 1965). The main purpose of the MCC is aligned with that of the World Health Organisation (WHO), which is to protect the public by ensuring that medicines sold in South Africa are safe, efficacious and of acceptable quality (WHO, 2013; DoH, 2013; MCC, 2013). This purpose is achieved by prescribing standards to govern the manufacture, distribution, sale and marketing of medicines through published guidelines. The MCC also determines the scheduling status of medicines and medicinal substances to control their prescribing and dispensing (MCC, 2013).

Part of the mandate of the MCC is to maintain the medicine register, register new medicines, amend entries made in the register, transfer registration certificates, cancel registration of discontinued medicines, approve labelling and advertising of medicines and authorize the sale of unregistered medicines under certain conditions (DoH, 2013). This is to ensure that the safety, quality and efficacy of registered medicines are maintained throughout their life-cycle. Changes which occur to these medicines after registration, must also comply with quality, safety and efficacy requirements as stipulated by the MCC (MCC Guideline 2.08, 2013:1).

Some technical changes that may take place after registration may be related to manufacturing, packaging and testing sites, manufacturing and testing methods and pharmaceutical ingredients and their sources. Clinical changes would affect package inserts and patient information leaflets. Package inserts are leaflets accompanying pharmaceutical products, which contain clinical information about the product. Clinical information includes indications, contraindications, dosing instructions, side effects and warnings. Patient information leaflets are an adaptation of the package insert into consumer language for patients. Changes to these documents would normally relate to safety of the medicine (MCC Guideline 2.01, 2013:23-26; MCC Guideline 2.16, 2013:1; MCC Guideline 2.14, 2013:4).

The MCC stipulates the format and data requirements in compiling applications for registration of medicines and applications to make changes to registered medicines, via published guidelines. These guidelines are based on the Medicines and Related Substances Act 101 of 1965 and its regulations (MCC Guideline 2.01, 2013:1).

The MCC aligns itself with established regulatory health authorities around the world, such as Food & Drug Administration (USA), European Union (EMA and National Regulatory Authorities), and MWH (Japan). It also aligns to Swissmedic (Switzerland), Health Canada (Canada) and Therapeutic Goods Association (Australia), to ensure that regulatory practices in South Africa are harmonized with internationally accepted standards (MCC Guideline 2.01, 2013:1&14).

The MCC is currently undergoing a transition to become a new public entity known as the South African Health Products Regulatory Agency (SAHPRA), which will manage registration, regulation and control of health products such as medicines and medical devices. Due to legislative changes that first need to be passed by Parliament, this transition may occur in 2013 (Schaay *et al.*, 2011:16).

2.3 Scope of Practice in Industry

In regulatory affairs practices in industry, pharmacists provide more than scientific and technical support to their internal and external stakeholders. Their scope of practice includes being familiar with legislation governing medicine registrations, compiling medicine registration applications for human, veterinary, biological or homeopathic medicine, managing the registration process, controlling pharmaceutical advertising, updating and maintaining regulatory licences and supporting the sales and marketing functions in a company (Health Science Academy, 2013). In addition, they are expected to be experts in the technology of the products they manage (Robinson 2006:18). It therefore stands to reason that their skill sets must be broader than scientific and technical qualifications.

Most companies operate on a multinational basis making exportation of medicines a key component of their business. This requires that regulatory affairs pharmacists continually monitor, analyse and interpret the practices and requirements of health authorities in their export markets in order to inform their internal stakeholders of regulatory trends and matters (Dheyongera, 2011:38).

The Marketing Code was issued by pharmaceutical trade associations in terms of the Medicines and Related Substances Act No 101 of 1965 to establish responsible, ethical and professional marketing of health products to healthcare professionals and the public. This Code takes into account advertising and labelling restrictions based on the scheduling status of medicines and the audience to which these medicines are advertised. For example, Schedule 0 medicines may be advertised directly to consumers, but Schedule 5 medicines may only be advertised to health care professionals with more restrictions to the content of the advertisement (SA Marketing Code, 2010: 5-7). A thorough understanding of the marketing code is required, since regulatory affairs is involved in developing marketing concepts and in approving advertising and packaging material (Dheyongera, 2011).

Globally, the regulation of medical products has been expanding since the early 20th century and has now 'mushroomed', resulting in significant strains on experienced regulatory affairs professionals. The shortage of regulatory affairs professionals is seen as 'massive' with the expectation that regulatory demands will continue to increase. (Robinson, 2006:18). In each country, the capacity to provide adequate pharmaceutical services depends on two workforce needs, that is an appropriately trained pharmacy workforce and a committed academic workforce to train new pharmacists (Anderson *et al.*, 2009, 7:45).

2.4 Regulatory education

Various studies around the world have shown that the lack of education in regulatory affairs is partially responsible for the shortage of regulatory affairs professionals. In the UK, pharmacy students do not seem to have sufficient information about the pharmaceutical industry, as most pharmacy schools give little attention to industrial pharmacy compared with other careers. Pharmacists in industry however, perceive regulatory affairs to be a prominent career opportunity. It is clear that undergraduates need to be made aware of the opportunities to develop their careers in regulatory affairs (Kirby-Smith, 2012).

In the US and Europe, continuing education by regulatory affairs organizations, has been useful in developing and maintaining the regulatory knowledge of their members (who are already involved in regulatory affairs), but a possible further solution may be to educate new regulatory affairs professionals in academic institutions. While practical experience is preferred over academic qualifications, employers and academic institutions are perceived to both bear the responsibility of filling the gaps by partnering with each other to meet the needs of students and prospective employers (Robinson, 2006: 20; 23).

In Australia, the Pharmaceutical Education Council (PEC) which was set up to assess the skills gap between government and tertiary institutions, maintains that “a lack of communication between industry and academia means that industry do not know what is available to them and academia do not know what industry wants”. They therefore encourage a two-way partnership between industry and academia. Of the technical skills found to be lacking in new graduates, training and experience in regulatory affairs featured at the top of the list (PEC, 2007:88,91,96,103).

In India, the pharmaceutical industry is a rapidly growing sector, making it part of the global competition. The pharmaceutical industry is one of the most highly regulated industries; coupled with the current global competition, the progressive need for regulatory affairs professionals cannot be over emphasized. It is of urgency that the current requirements of pharmaceutical industries be incorporated into the standard curriculum of pharmacy schools. To address this issue, two universities in India have taken initiatives to offer Pharmaceutical Regulatory Affairs as a subject in a post-graduate course (Songara 2011:122-123).

In South Africa, no published articles were found to describe possible inconsistencies in the current regulatory framework, such as a comparison of legislative requirements, pharmacy education and industry practices.

With regard to pharmacy education however, courses offered by pharmacy schools are registered and approved by the South African Pharmacy Council (SAPC) for professional reasons. The SAPC is responsible for establishing and overseeing standards for education and license registrations (Summers, 2001:150-154). It conforms to The Pharmacy Act (Act 53 of 1974), which was amended in 1997 for provisions relating to pharmacy education and training requirements for registration (Pearmain, 2012:27). The amendment included the addition of seven unit standards, which were prescribed for the education and training of pharmacists to form their scope of practice (Government Gazette, 20 November 2000, No. 21754).

Regulatory practices in industry however, are determined by the guidelines published by the MCC in keeping with the Medicines and Related Substances Control Act (Act 101 of 1965), as mentioned earlier, and not The Pharmacy Act. It was also noted in a local publication that for some inconsistencies in health legislation, possible amendments may be required to The Pharmacy Act to bring it in line with The Medicines and Related Substances Act (Pearmain, 2012: 26).

~~Examination of regulatory affairs legislation, which includes the Pharmacy Act and the Medicines and Related Substances Act, may aid in identifying some possible reasons for the educational and skills gaps in the current regulatory framework in South Africa. Other key areas to examine may be job descriptions compiled by pharmaceutical companies and the undergraduate curriculum of the Bachelor of Pharmacy degree offered by Pharmacy schools in South Africa.~~
Key areas to assess the correlation between education and regulatory practices in industry, would be job descriptions compiled by pharmaceutical companies and the undergraduate curriculum of the Bachelor of Pharmacy degree offered by Pharmacy schools in South Africa.

~~The aim of this study is to assess if there are inconsistencies in regulatory affairs, with current legislation, the undergraduate pharmacy curriculum and job descriptions of regulatory affairs pharmacists; to determine if graduating pharmacists, entering industrial pharmacy are equipped for their role in regulatory affairs.~~
The aim of this study in assessing this correlation is to determine if graduating pharmacists, entering industrial pharmacy are equipped for their role in regulatory affairs.

At the end of the study, proposals to improve the training and performance of regulatory affairs pharmacists in the affected sectors will be presented if needed.

HYPOTHESIS

Pharmacist tertiary education and pharmaceutical industry requirements are not sufficiently correlated to allow pharmacists entering the pharmaceutical industry to be equipped for their role in regulatory affairs.

3. STUDY OBJECTIVES

~~1. Compare regulatory function determinants across the relevant sectors viz. education, government and industry as detailed below under points i to iv. This will be to assess inconsistencies and compliance in the required competencies of a regulatory affairs pharmacist.~~

- ~~i. — The appropriate section in Pharmacy curriculum from all eight Pharmacy schools in South Africa to assess the level to which regulatory affairs is taught~~
- ~~ii. — The scope of practice of regulatory affairs pharmacists as stipulated by the Pharmacy Act and the South African Pharmacy Council~~
- ~~iii. — The Medicines and Related Substances Act and current MCC guidelines, to assess the main regulatory functions required in pharmaceutical companies in South Africa.~~
- ~~iv. — Job descriptions of regulatory affairs pharmacists to assess the functional competencies required.~~

~~Present proposals to improve the training and performance of regulatory affairs pharmacists in the affected sectors if needed.~~

Compare regulatory education and industrial practices as follows to assess deficiencies in the required competencies of a regulatory affairs pharmacist.

- i. The appropriate section in Pharmacy curriculum from all eight Pharmacy schools in South Africa to assess the level to which regulatory affairs is taught
- ii. Job descriptions of regulatory affairs pharmacists to assess the functional competencies required.

4. METHODS

~~In order to compare regulatory function determinants in the education, government and industry sectors, to assess inconsistencies and compliance in the competencies of a regulatory affairs pharmacist, an investigative survey study will be conducted as follows:~~

In order to compare regulatory education and industrial requirements of a regulatory affairs pharmacist, an investigative survey study will be conducted as follows:

4.1. Acquisition of academic curriculum

In order to review the extent to which regulatory affairs is taught, Heads of Department of Pharmacy at the Universities of Witwatersrand, Western Cape, Limpopo, Kwazulu-Natal, North West, Rhodes and Nelson Mandela Metropolitan Universities (SAPC 2012) will be contacted and permission acquired to obtain copies of the undergraduate curriculum for Pharmacy Practice from 1st year to 4th year. This request will include details of duration and content of pharmacy practice courses relating specifically to regulatory affairs (See Appendix 1). The undergraduate curriculum from the eight pharmacy schools will be tabulated to demonstrate common and different modules / themes so that regulatory functions can be grouped together and highlighted. Pharmacy schools which provide regulatory affairs education at a post graduate level will also be requested to provide copies of their curriculum for comparative review,

In order to assess their awareness of the functions of regulatory affairs pharmacists and the level to which regulatory affairs is taught, questionnaires will be sent to academic staff responsible for teaching pharmacy practice (See Appendix 2). To ensure maximum receipt of responses, telephonic or electronic reminders will be sent where necessary.

~~4.2. Examination of the undergraduate curriculum in light of the official Scope of Practice for Pharmacists:~~

~~The undergraduate curriculum will be examined against The Pharmacy Act and the Good Pharmacy Practice Guidelines and the Good Manufacturing Practices guideline which are published by the South African Pharmacy Council and the MCC respectively. These documents will be used as they prescribe the scope of practice which pharmacists in South Africa are required to engage in. Information will be extracted from the relevant documents to assess the level to which regulatory affairs is covered in the undergraduate curriculum.~~

4.2. Assessment and comparison of current regulations with job descriptions, prescribed scope of practice and undergraduate curriculum.

Pharmaceutical companies and relevant contact details will be identified on the list of pharmaceutical companies registered with the South African Pharmacy Council, which is available on request at a minimal cost. All pharmaceutical companies will be sent letters and survey questionnaires and once responses are received, they will be assessed for eligibility into the study by review of their responses to the inclusion and exclusion criteria which they will be required to provide. These criteria are described further on in this section.**4.3.**

~~Examination of Regulations and Guidelines to determine requirements by pharmaceutical companies.~~

~~The Medicines and Related Substances Act and its regulations will be examined to determine the functions to be carried out by regulatory affairs departments such as regulatory practices in labelling, advertising and dossier compilations. The MCC guidelines will be examined to summarise regulatory functions in compiling technical and clinical data for dossiers, and to review key areas of dossier maintenance during product life cycle, whilst the SA Marketing Code will be examined to summarise the functions required by regulatory affairs in approving promotional material for advertising. Information from these documents will be extracted to summarise requirements in the key functional areas in regulatory, which are directly impacted by legislation.~~

Pharmaceutical companies (local and multi-national) will be requested to provide job descriptions for staff in their regulatory affairs department. This will be to assess company requirements to fulfill the functions of a regulatory role. Letters will be addressed to The Responsible Pharmacist / Human Resources Manager, stating the purpose of study and requesting copies of job descriptions for regulatory affairs pharmacists (Appendix 3). To ensure ~~promptness in receiving responses~~ maximum receipt of responses, telephonic or electronic reminders will be sent where necessary and appropriate.

In order to cover various types of pharmaceutical manufacturers and medicinal products, pharmaceutical companies will be selected according to the types of pharmaceutical products that they manufacture viz. ethical medicines, generic medicines and consumer (OTC) health products.

Inclusion criteria will be pharmaceutical companies, which are registered with SAPC, which have a central in-house regulatory department, and which manufacture or import ethical, generic or consumer (OTC) medicines. ~~Exclusion criteria will be pharmaceutical companies, which are not registered with SAPC, which outsource their regulatory affairs functions and / or which do not manufacture or import ethical, generic or consumer (OTC) medicines.~~ Exclusion criteria will be pharmaceutical companies which manufacture or import biological medicines, medical devices, veterinary medicines and complementary medicines.

Pharmaceutical companies will be assessed for inclusion and exclusion criteria based on the feedback provided on the first page of the survey questionnaire (Appendix 4). Companies which are not eligible will be eliminated from the study. There are currently 267 manufacturing pharmacies, which are registered with SAPC (SAPC, 2012). The following

formula will be used to calculate the number of pharmacies required to participate in this study (sample size) to obtain a 5 % statistical significance (or 95 % confidence level) (Survey system website, 2012). It was determined in consultation with a Wits statistician that should all 267 pharmaceutical companies currently registered with SAPC, be eligible to participate, 265185 responses per question will be required to obtain statistical significance.

~~There are currently 267 manufacturing pharmacies, which are registered with SAPC (SAPC, 2012). The following formula will be used to calculate the number of pharmacies required to participate in this study (sample size) to obtain a 5 % statistical significance (or 95 % confidence level) (Survey system website, 2012).~~

$$n^* = \frac{z^2 p(1-p)}{d^2}$$

Where Z = 1.96 (e.g. 1.96 for 95% confidence level)

p = 0.5 (proportion of pharmaceutical companies that have the outcome of interest)

d = 0.04 (4% precision allowed)

Adjusting for the population size, the minimum sample size will be

$$Ss = \frac{n^*}{1 + \frac{n^*}{N}}$$
 where n^ is the sample size calculated and N is the number of eligible*

pharmaceuatical companies.

The actual sample size will be finalised once the inclusion and exclusion criteria have been considered for each company. The number of eligible companies will be counted and if it is found that these total less than 185, all eligible companies will be included in the study. Letters will in any event be sent to all eligible companies.

~~The inclusion and exclusion criteria will further determine the actual sample size to be used and should all 267 pharmaceutical companies currently registered with SAPC, be eligible to participate, 265 responses per question will be required to obtain statistical significance. The actual sample size will be finalised once the inclusion and exclusion criteria have been considered for each company.~~

Details of job descriptions will be tabulated to compare them with each other in terms of common functions and specialized functions, according to the type of pharmaceutical products manufactured, to identify key areas of commonality. ~~These job descriptions will~~

~~then be compared with the undergraduate curriculum and prescribed scope of practice to determine whether regulatory functions are covered in the curriculum and prescribed scope of practice. Job descriptions will be compared to the current regulatory affairs requirements to assess if there are any inconsistencies. These job descriptions will then be compared with the undergraduate curriculum and prescribed scope of practice to determine the extent to which regulatory functions are covered in the curriculum.~~

Questionnaires will be sent to heads of regulatory affairs at the same pharmaceutical companies selected to request job descriptions, in order to determine their view on the level of competence found in recent graduates employed as regulatory affairs pharmacists (Appendix 4). As with the request for job descriptions, telephonic or electronic follow up and personal interviews will be conducted where necessary and appropriate.

Once results have been collated and analysed, the sectors showing the greatest need for improvement in exposure to regulatory affairs, will be assessed individually for specific deficiencies and solutions proposed. Proposals for collaboration between pharmacy schools and industry will be offered, and willingness to participate will be assessed in advance in the study questionnaires. Details of the pharmacy schools and pharmaceutical companies which opt to collaborate will be provided to the South African Pharmacy Council to allow co-ordination of this where possible.

5. DATA ANALYSIS

For easy comparison, results from the various surveys will be tabulated for responses to each question according to the options provided and compared to the published regulatory requirements. For qualitative analysis, comparison of responses will be collated, and for quantitative analysis, statistics will be done to determine if there is significance in the responses. Qualitative data will be used to support quantitative where relevant. A statistician will be consulted for advice on the appropriate test to be used to analyse noticeable trends for key questions.

A WITS statistician was consulted for advice on the appropriate tests to be used to analyse noticeable trends for key questions and it was decided that frequencies, means and medians will be the primary means of descriptive analysis.

For the survey to the pharmacy schools, analysis will involve either summary stats of each item (frequencies or mean/median score) or items will be grouped into themes and the total score calculated for each theme. An analysis of the of the total score (means/median of the

total score) will then be analysed. Depending on the number of respondents, summaries will be done per school, but if the number of schools participating are small, an overall summary for all the schools will be done.

To explore relationships between different outcomes, chi-square tests of association will be used. If the sample size is small the Fisher's Exact test will be used instead of Chi Square.

For the open ended questions, thematic analysis will be done to pick out popular suggestions. These will then be coded and frequency analysis will be performed.

Frequencies and percentages will be used to analyse the eligibility of pharmaceutical companies based on the inclusion and exclusion criteria options chosen.

The analysis of the questionnaires on regulatory affairs will be either frequencies or means/median scores or means/median of total score. Analysis of the job description will involve frequencies and percentages since the responses are all categorical.

For the section relating to competence of recent graduates, each possible response is a variable (0 or 1). Therefore summary stats frequencies and percentages will be used for each response.

6. ETHICS

~~Submission to the Ethics committee will be done in January 2013.~~

Submission to Ethics committee was done in June 2013. Ethics approval was granted on 07/08/2013. The clearance certificate number is M130655.

7. TIMING

	Oct 2012	Nov 2012	Dec 2012	Jan 2013	Feb 2013	Mar 2013	Apr 2013	May 2013	Jun 2013	Jul - Dec 2013	Jan- Feb 2014	Mar- April 2014	May- June 2014	Jul – Aug 2014
Literature Review														
Prepare Protocol														
Protocol Assessment														
Ethics Application														
Data Collection														
Data Analysis														
Writing up – Thesis														
Writing up – Paper														

8. FUNDING

~~Anticipated costs for the following will be covered by a grant (to be applied for from Faculty) or self-funded:~~

~~— Telephone calls to source contact information for pharmacy schools and pharmaceutical companies, to personally address letters and surveys~~

~~— R 500.00~~

~~— Postal and / or electronic deliveries of letters and questionnaires to pharmacy schools and pharmaceutical companies; postal stamps and envelopes and / or electronic data — R 1 000.00~~

~~— Printing costs — R 200.00~~

~~— Travel costs for personal interviews and completion of surveys for pharmaceutical companies based in Cape Town — R 1 000.00 (R3.17 / km)~~

8. FUNDING

Anticipated costs for the following will be covered by a grant (to be applied for from Faculty) or self-funded:

No.	Expense	Estimated Cost
1.	Telephone calls to source contact information for pharmacy schools and pharmaceutical companies.	R 500.00
2.	Postal and / or electronic deliveries of letters and questionnaires to pharmacy schools and pharmaceutical companies.	R 1 000.00
3.	Printing costs	R 200.00
4.	Travel costs for personal interviews and completion of surveys (R 1 000.00 (R3.17 / km)	R 1 000.00
5.	TOTAL	R 2 700.00

9. PROBLEMS

- Identifying a key contact person in each organization / institution to facilitate communication may cause delays in initiating the study.
- Confidentiality code by various sectors / organisations could inhibit the level of transparency of information provided.
- Perception of study may be seen as demeaning to some sectors / organisations, resulting in reluctance to provide honest responses.
- Response rate and numbers may slow down processing of results and progress of study

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Appendix 1 – Example letter to Pharmacy schools

The Head of Pharmacy Department
 Faculty of Health Sciences
 Medical School - Wits University
 7 York Road
 Parktown
 2193

Dear Sir / Madam

Re: Participation in Study - B.Pharm Undergraduate Curriculum - Regulatory Affairs

I am a postgraduate student at the University of the Witwatersrand currently studying towards an MSc.Med degree in Pharmacotherapy. As part of my studies, I am required to complete a research project. My research topic is "~~Assessment of legislation, education and industry practices to identify inconsistencies in meeting regulatory affairs requirements~~" "Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists"

This topic entails examining the current undergraduate curriculum in all pharmacy schools in South Africa in order to determine the extent to which Regulatory affairs is taught.

I would be grateful for your contribution to this study by providing details of content and duration of subjects covered in the Pharmacy Practice (or similar) module of the B.Pharm degree from 1st year to 4th year. Should regulatory affairs be covered in any other module or course (including post graduate courses), kindly indicate this and provide the subjects for that particular module or course.

Please also see attached a short questionnaire to be completed in order to further contribute to the outcome of this study.

Please note that all information provided will be kept in strict confidence for use by myself and my supervisors for the sole purpose of this study. No information will be disclosed to any other persons or entities.

At the end of the study we will forward you with results of the outcome and any recommendations that could be made to complement your current curriculum.

Please could you kindly return responses for curriculum content as well as completed questionnaire to me as soon as convenient for you. My deadline for collating this information is the ~~31st March 2013~~ 31st March 2014. My e-mail address is marlenem1810@gmail.com. I look forward to your kind co-operation in this study.

Yours faithfully

Marlene Moonsamy (082-321-1789)

Mrs N. Padayachee (084-230-2364)

Assoc. Prof. R. van Zyl (083-312-0228)

Appendix 2 – Example Questionnaire 1 – Pharmacy Schools.

Date: _____

Name of Person completing questionnaire: _____

Designation of Person completing questionnaire: _____

Name of Pharmacy School: _____

Thank you for choosing to participate in this study. The following questions are based on your role in co-ordinating the curriculum for pharmacy students.

SECTION A

The following five options are represented as **A₁**, **B₂**, **C₃**, **D₄** or **E₅**.

Please choose your best option for each question below by indicating **A₁**, **B₂**, **C₃**, **D₄** or **E₅** in the response column on the right.

A₁ = strongly agree, **B₂** = agree, **C₃** = neutral, **D₄** = disagree, **E₅** = strongly disagree

	QUESTION	RESPONSE
1.	I am familiar with the concept of regulatory affairs in pharmaceutical industry	
2.	I am familiar with the requirements of regulatory affairs in industry	
3.	I am familiar with the various acts governing regulatory practice in South Africa.	
4.	I am familiar with the different and changing formats of the registration dossier viz. MBR1, MRF, CTD, eCTD.	
5.	I am familiar with the content of the registration dossier for the various formats - MBR1, MRF, CTD, eCTD.	
6.	I understand the role and functions of the MCC (Medicines Control Council)	

7.	I am familiar with the guidelines published by the MCC	
8.	I am familiar with the various trade associations, which exist to support the pharmaceutical industry in SA, including SAPRAA (South African Pharmaceutical Regulatory Affairs Association).	
9.	I am familiar with the SA Marketing Code of Practice, which regulates the advertising of medicines in South Africa.	
10.	I am aware of the need for pharmacy students in South Africa to be well equipped in regulatory affairs functions by the time they graduate.	
11.	The undergraduate B.Pharm curriculum at this pharmacy school consists of a regulatory affairs module, which covers the main requirements of regulatory functions.	
12.	This school provides regulatory affairs education at a post graduate level.	
13.	I am willing to collaborate with the pharmaceutical industry and trade associations to develop a curriculum for regulatory affairs, should there be a need.	

SECTION B

Please make suggestions (if any) for areas in regulatory to be included in a future regulatory affairs module of the B. Pharm undergraduate curriculum:

Appendix 3 – Example Letter to Pharmaceutical companies

The Human Resource Manager / Responsible Pharmacist

"Company name"

"Address"

"Address"

"Address"

Dear Sir /Madam

RE: Participation in Study - Regulatory Affairs Pharmacist - Job Description

I am a postgraduate student at the university of the Witwatersrand, currently studying towards an MSc.Med degree in Pharmacotherapy. As part of my studies, I am required to complete a research project. My research topic is ~~"Assessment of legislation, education and industry practices to identify inconsistencies in meeting regulatory affairs requirements"~~ "Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists"

This topic entails examining job descriptions of regulatory pharmacists in various pharmaceutical companies in South Africa, in order to determine the level of expertise required to perform Regulatory affairs functions.

I would be grateful for your contribution to this study ~~by providing detailed job description/s of regulatory affairs pharmacists in your organization.~~ by ticking the following boxes to indicate key regulatory functions which are practiced and comprised in the job description of regulatory affairs pharmacists in your organization.

<u>No.</u>	<u>Job Function of Regulatory Affairs Pharmacist</u>	<u>Yes</u> <u>(✓)</u>	<u>No</u> <u>(✓)</u>
<u>1.</u>	<u>Preparation of medicine registration dossiers for submission to MCC.</u>		
<u>2.</u>	<u>Preparation of medicine registration dossiers for submission to health authorities out of South Africa (export markets).</u>		
<u>3.</u>	<u>Preparation of pharmaceutical amendments of dossiers to submit to MCC (to ensure update of pharmaceutical information in dossier and ensure Quality compliance)</u>		
<u>4.</u>	<u>Preparation of pharmaceutical amendments of dossiers to submit to health authorities out of South Africa (export markets)</u>		
<u>5.</u>	<u>Preparation of clinical amendments / package insert updates to submit to MCC (to ensure update of clinical information in dossier and to ensure Safety & Efficacy compliance)</u>		
<u>6.</u>	<u>Preparation of clinical amendments / package insert updates to submit to health authorities out of South Africa (export markets)</u>		
<u>7.</u>	<u>Approval of Promotional Material for South Africa (Marketing Support)</u>		
<u>8.</u>	<u>Approval of Promotional Material for export markets (Marketing Support)</u>		
<u>9.</u>	<u>Submission and approval of labelling and printed packaging updates.</u>		
<u>10.</u>	<u>Re-registration and licence renewal of products for export markets</u>		
<u>11.</u>	<u>PSUR submissions and Pharmacovigilance support</u>		
<u>12.</u>	<u>Regulatory Intelligence – provide regulatory and/or source legal advice when required.</u>		
<u>13.</u>	<u>Competitor Challenges (co-ordinate the legal process)</u>		
<u>14.</u>	<u>Engage in and support new product launch activities with local, regional and global business.</u>		

Please add any additional regulatory functions not listed above:

Please also see attached a short questionnaire to be completed in order to further contribute to the outcome of this study.

Please note that all information provided will be kept in strict confidence for use by my supervisors and myself for the sole purpose of this study. No information will be disclosed to any other persons or entities.

At the end of the study, upon your request we will forward you the results of the outcome and any recommendations that could be made to complement current regulatory affairs practices in industry.

Please could you kindly return responses for job descriptions as well as completed questionnaire to me as soon as convenient for you. My deadline for collating this information is the ~~31st March 2013~~ 31st March 2014.

My e-mail address is at marlenem1810@gmail.com.

I look forward to your kind co-operation in this study.

Yours faithfully

Marlene Moonsamy (082-321-1789)

Mrs. N. Padayachee (084-230-2364)

Assoc. Prof. R. van Zyl (083-312-0228)

Appendix 4 – Example Questionnaire 2 – Pharmaceutical Companies

Date: _____

Name of Person completing questionnaire: _____

Designation of Person completing questionnaire: _____

Name of Pharmaceutical Company: _____

Please answer the following questions about your company by ticking the appropriate box(es):

- Company registered with SAPC as a manufacturing pharmacy?
YES ☐ NO ☐
- In-house Regulatory Affairs Department present?
YES ☐ NO ☐
- Products manufactured:
ETHICAL MEDICINES ☐ GENERIC MEDICINES ☐
OTC / CONSUMER MEDICINES ☐ OTHER ☐
Please provide details for OTHER (if applicable): _____

Thank you for choosing to participate in this study. The following questions are based on your experience as a key leader in regulatory affairs in your organization.

SECTION A

The following five options are represented as A1, B2, C3, D4 or E5.

Please choose your best option for each question below by indicating A1, B2, C3, D4 or E5 in the right margin.

A1 = strongly agree, B2 = agree, C3 = neutral, D4 = disagree, E5 = strongly disagree

	QUESTION	RESPONSE
1.	Regulatory Affairs functions are key to a pharmaceutical company as it lays down the basis for all other pharmaceutical functions, and ensures that the company is legally compliant to commence business.	
2.	It is critical for the reputation of the business & the pharmaceutical industry that regulatory affairs be given adequate and competent resources to carry out their functions.	
3.	Regulatory affairs functions are taught in pharmacy schools at an undergraduate level.	
4.	Regulatory affairs functions are taught in pharmacy schools at a post graduate level.	
5.	I suggest that regulatory affairs be taught as a specialization in pharmacy at an undergraduate level, in order to have more competent graduates entering the pharmaceutical industry sector.	
6.	It is better to train regulatory affairs pharmacists fully only once they enter the pharmaceutical industry due to the nature of the work.	
7.	Recent graduates (straight out of university), that I employed as regulatory affairs pharmacists were competent for their role.	

8.	Recent graduates (straight out of varsity), that I employed as regulatory affairs pharmacists were not competent, but were familiar to some degree with regulatory affairs, due to academic learning e.g. intern programme.	
9.	Recent graduates (straight out of varsity), that I employed as regulatory affairs pharmacists were not competent, but were familiar to some degree with regulatory affairs, due to their prior exposure to the pharmaceutical industry	
10.	It currently takes on average the following time period for new regulatory affairs pharmacists to become fully competent in their role:	
10.1	0 to 6 months	
10.2	6 to 12 months	
10.3	12 to 24 months	
10.4	24 to 36 months	
10.5	more than 36 months	
10.1	It currently takes on average 0 to 6 months for new regulatory affairs pharmacists to become fully competent in their role.	
10.2	It currently takes on average 6 to 12 months for new regulatory affairs pharmacists to become fully competent in their role.	
10.3	It currently takes on average 12 to 24 months for new regulatory affairs pharmacists to become fully competent in their role.	
10.4	It currently takes on average 24 to 36 months for new regulatory affairs pharmacists to become fully competent in their role.	

10.5	It currently takes more than 36 months for new regulatory affairs pharmacists to become fully competent in their role.	
11.	I am willing to collaborate with pharmacy schools to develop a curriculum for undergraduate students, should there be a need.	

SECTION B

Please complete the following sections for further details to above responses

1. With reference to responses in Question 7, 8 & 9 of the survey above, please tick the appropriate boxes below:

Recent graduates were mostly <u>competent</u> in:		Recent graduates were mostly <u>incompetent</u> in:	
Knowledge of legislation	☐	Knowledge of legislation	☐
Dossier Compilation	☐	Dossier Compilation	☐
Production support	☐	Production support	☐
Supply Chain support	☐	Supply Chain support	☐
Quality Assurance support	☐	Quality Assurance support	☐
Marketing support	☐	Marketing support	☐
Pharmaceutical knowledge	☐	Pharmaceutical knowledge	☐
Clinical knowledge	☐	Clinical knowledge	☐
Other (please elaborate below):	☐	Other (please elaborate below):	☐

Other (competent): _____

Other (incompetent): _____

2. Please make suggestions (if any) for areas in regulatory to be included in a future regulatory affairs module of the B. Pharm undergraduate curriculum:



UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
FACULTY OF HEALTH SCIENCES
ASSESSORS MEETING

CANDIDATE: MOONSAMY

Date of Assessor Group Meeting: 20/2/13

School: THERAPEUTIC SCIENCES

☐ Yes ☒ No Is the research question clearly identified and described?

Comments:

Need to redefine the title of the research

☐ Yes ☐ No ☒ Not entirely

Is the design of the study and methods the methods used appropriate for the research question being asked?

Comments:

More detail in methods

Need to do a new job description

Is the study feasible within: YES

i. the applicant's resources?

☒ Yes ☐ No

ii. the departments resources?

☒ Yes ☐ No

iii. the time frame?

☒ Yes ☐ No

Moonsamy, Marlene [CONZA]

From: Irene Janse Van Noordwyk <Irene.JanseVanNoordwyk@wits.ac.za>
Sent: Thursday, September 12, 2013 10:42 AM
To: Moonsamy, Marlene [CONZA]
Cc: Robyn Van Zyl
Subject: Revised Protocol: Feedback

Dear Ms Moonsamy

First please let me apologise for the delay in responding, but I was waiting for comments from one of the Assessors. The Assessors approved your revised protocol subject to some minor corrections (listed below) to the satisfaction of the supervisor:

1. The student has merely repeated each comment as far as I can tell (as there is no evidence of the original comments), rather than responding to each comment, so one has to scroll through both versions of the protocol to see what she has actually changed. There is no indication if she has or has not addressed each comment. She has also not highlighted the changes which would have assisted in this process.
2. On closer review, it is apparent that the student has NOT addressed all the comments satisfactorily. For example, the objectives, as written in the revised protocol, are not objectives at all – they are steps that will be followed to achieve the aim, and need to be revised (comment no.6); the issue of electronic reminders remains (comment no. 7) – again, with no explanation from the student, one cannot assess her ‘non’ response; she has misinterpreted the issue of inclusion vs exclusion criteria (comment no. 9); the number of samples has been increased (comment no. 10) but the student has not said that this is due to a recalculation or explained what was wrong with the initial calculation.
3. The timing is out again due to the long delay (comment 12 and 13) although this is not the fault of Miss Moonsamy.

Please submit 1 electronic copy (protocol & letters only to STSProtocol@gmail.com) and 1 hard copy of your revised protocol, letter of corrections and supporting letter from your supervisor to me (Room 3B28, Level 3, Medical School).

Kind Regards

Irene



This communication is intended for the addressee only. It is confidential. If you have received this communication in error, please notify us immediately and destroy the original message. You may not copy or disseminate this communication without the permission of the University. Only authorised signatories are competent to enter into agreements on behalf of the University and recipients are thus advised that the content of this message may not be legally binding on the University and may contain the personal views and opinions of the author, which are not necessarily the views and opinions of The University of the Witwatersrand, Johannesburg. All agreements between the University and outsiders are subject to South African Law unless the University agrees in writing to the contrary.



Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

24 February 2014
Person No: 0208316J
TAA

Miss MR Moonsamy
P O Box 12762
Edleen
Kempton Park
1625
South Africa

Dear Miss Moonsamy

Master of Science in Medicine: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of **Master of Science in Medicine** has been approved:

From:

To: **Correlation between tertiary education and pharmaceutical industry requirements
for regulatory affairs pharmacists**

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sandra Benn'.

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences



Postgraduate Office, Faculty of Health Sciences

Wits Medical School, 7 York Road, PARKTOWN, 2193, Johannesburg • Tel: (011) 717 2000 • Fax: (011) 717 2119

APPLICATION FOR CHANGE OF TITLE OF APPROVED RESEARCH REPORT, DISSERTATION OR THESIS

Motivation / Reason for title change:

Title change was requested by Assessors at the Assessor meeting on 20 February 2013, to be more consistent with the revised scope and objectives of the study. Only two areas viz. education and industry requirements are to be examined (not legislation.)

Recommendation of Department / School:

this is supported by Dept

Student Surname and Initials: Moonsamy M.R Student Number: 0208316J

Degree: MSc. Med. Pharmacotherapy

Department: Pharmacy & Pharmacology Telephone: 0823211789 E-mail: marlenem1810@gmail.com

Previous Title:

Assessment of legislation, education and industry practices to identify inconsistencies in meeting regulatory affairs requirements

New Title:

Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists

Supervisor/s: Assoc. Prof. R van Zyl Mrs. N. Padayachee

Departments: Department of Pharmacy & Pharmacology Department of Pharmacy & Pharmacology

Supervisor's Telephone: 011 717 2271 011 7172269

Supervisor's E-mail: Robyn.VanZyl@wits.ac.za Neelaveni.Padayachee@wits.ac.za

Signatures of Student: _____ Supervisor 1: R van Zyl Supervisor 2: Padayachee

*HEAD OF DEPARTMENT / HEAD OF SCHOOL: *(Where the HOD is Supervisor, the HOS must sign)

DANCKWERTS M.P.
(Surname and Initials)

[Signature]
(Signature)

4/6/13
(Date)

DECISION OF CHAIR OF THE PG COMMITTEE: _____ Signature: _____

Date: _____



R14/49 Ms Marlene Rose Moonsamy

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130655

NAME: Ms Marlene Rose Moonsamy
(Principal Investigator)

DEPARTMENT: Pharmacy and Pharmacology
 Johnson and Johnsons (PTY) Ltd

PROJECT TITLE: Correlation between Tertiary Education and
 Pharmaceutical Industry Requirements
 for Regulatory Affairs Pharmacists

DATE CONSIDERED: 28/06/2013

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Prof van Zyl/Mrs Padayachee

APPROVED BY: 
 Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 07/08/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature _____

Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES



Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

24 January 2014
Person No: 0208316J

Miss MR Moonsamy
P O Box 12762
Edleen
Kempton Park
1625
South Africa

Dear Miss Moonsamy

Confirmation of details of registration

I am pleased to confirm the details of your registration as at 24 January 2014 in the Faculty of Health Sciences for the **Master of Science in Medicine, Year of Study 1, Part-Time** for the year 2014.

According to our records you are registered for the following courses:

Course Code	Course Description	Class	Calendar
PACY7026	Research Report	GEN	Full Year-2014

Field of Study: Pharmacotherapy

Milestone	Due Date	Achieved Date
Submission of Research Proposal	2010-12-27	
Submission of Research	2011-12-22	
Appointment of Examiner	2011-10-23	
Progress Report Student	2011-04-26	

Should there be any inaccuracies contained in this letter, please contact the Faculty Office as soon as possible.

You are reminded that if you wish to withdraw from a course and if you are permitted by your faculty, you must complete the appropriate form that is available from the Faculty Office. Please consult the Fees Booklet regarding cancellation deadlines. You are also reminded to notify the Faculty Office in writing of any changes of address and, in addition, you are requested to check carefully that your name **Marlene Rose Moonsamy** is correct. This name must conform with that printed on your birth/marriage certificate as, unless you are registered as an occasional student, it is the name that will be printed on your graduation certificate.

If you have not already obtained your student card for this year, please do so as soon as possible. You must take this letter with you as proof of your registration.

I wish you every success in your studies at Wits.

Yours sincerely

A handwritten signature in black ink, appearing to read 'S. Benn', with a short horizontal line underneath.

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 4: Ethics Clearance



R14/49 Ms Marlene Rose Moonsamy

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130655

NAME: Ms Marlene Rose Moonsamy
(Principal Investigator)

DEPARTMENT: Pharmacy and Pharmacology
 Johnson and Johnsons (PTY) Ltd

PROJECT TITLE: Correlation between Tertiary Education and
 Pharmaceutical Industry Requirements
 for Regulatory Affairs Pharmacists

DATE CONSIDERED: 28/06/2013

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Prof van Zyl/Mrs Padayachee

APPROVED BY: 
 Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 07/08/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature _____

Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 5: Approval of Title - 2016

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG



Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

19 February 2016
Person No: 0208316J
TAA

Miss MR Moonsamy
P O Box 12762
Edleen
Kempton Park
1625
South Africa

Dear Miss Moonsamy

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Yours sincerely

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Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences